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September 10, 2003

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U.S. Environmental Protection Agency  
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Washington, DC 20460-0001

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RE: Diethanolamine—Subchronic Inhalation Study With Rats

Attention: TSCA 8(e) Coordinator



Dear Sir or Madam:

The American Chemistry Council hereby submits this letter regarding diethanolamine (CAS No. 111-42-2) on behalf of its Alkanolamines Panel. The letter is intended to inform EPA of certain findings from a subchronic study in which rats were administered diethanolamine by inhalation exposure. The Agency may regard this information as reportable under the provisions of TSCA Section 8(e). While the information is being submitted in accordance with the Agency's interpretation of relevant TSCA 8(e) guidance, the Panel has not made a determination as to whether a significant risk of injury to health or the environment is actually presented by the findings.

The member companies of the Alkanolamines Panel consist of: BASF Corporation, The Dow Chemical Company, Equistar Chemicals LP, Huntsman Corporation, and Ineos LLC.

The information reported here comes from the final report of a 90-day inhalation study sponsored by CEFIC (European Chemical Industry Council). The report is titled: *Diethanolamine – Subchronic inhalation toxicity study in Wistar rats, liquid aerosol/vapor exposure. Study focus on irritation of upper respiratory tract.* The final report is appended to this letter.

The final report states the following in section 1, page 14:

"Substance related pathological findings were confined to the larynx, in which squamous metaplasia and inflammatory cell infiltration at the base of the epiglottis was observed at the high concentration (8 mg/m<sup>3</sup>). This change is considered to be an adverse effect due to the concurrence of epithelial change and inflammatory response. However it is considered to be borderline because it showed full reversibility during the 3-month recovery period.

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The intermediate concentration (3 mg/m<sup>3</sup>) led to a reversible focal squamous metaplasia at the base of the epiglottis without inflammation in a minority of male animals (3 of 10) examined at the end of the exposure period. This change is considered to represent an adaptive response, rather than a frank adverse effect.

No substance related histopathology was present at the low concentration (1.5 mg/m<sup>3</sup>)."

If you have any questions about this submission, please contact me at (703) 741-5633 or at [jon\\_busch@americanchemistry.com](mailto:jon_busch@americanchemistry.com).

Sincerely,



Jon Busch  
Manager, Alkanolamines Panel  
Director, CHEMSTAR Panels

Attachment

99125\_DEA\_INT\_90dAerosol.doc

**STUDY TITLE****Report**

**Diethanolamine - Subchronic inhalation toxicity study in Wistar rats**  
liquid aerosol / vapor exposure  
Study focus on irritation of upper respiratory tract

**DATA REQUIREMENT**

inhalation exposure following  
OECD - Guideline method 413  
EEC Guidelines 87/302/EEC  
U.S. EPA OPPTS Guidelines 870.3465  
examinations according to the aim of the study

**AUTHORS**

Dr. A.O. Gamer (Study Director)  
Dr. E. Leibold  
Dr. W. Kaufmann  
Dr. B. van Ravenzwaay

**STUDY COMPLETED ON**

April 02, 2002

**PERFORMING LABORATORY**

Experimental Toxicology and Ecology  
BASF Aktiengesellschaft  
67056 Ludwigshafen/Rhein, Germany

**LABORATORY PROJECT IDENTIFICATION**

51I0299/99125

**SPONSOR**

CEFIC Amines Sector Group  
Avenue E. Van Nieuwenhuyse 4  
B- 1160 Brussels

**VOLUME I OF III  
(REPORT SECTION AND SUMMARY TABLES)**

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**GLP COMPLIANCE STATEMENT**

This study was conducted in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act).

.....C. J. ... April 2<sup>nd</sup>, 2002  
Study Director

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**SIGNATURE PAGE**

Study Director:

  
Dr. med. vet. A.O. Gamer

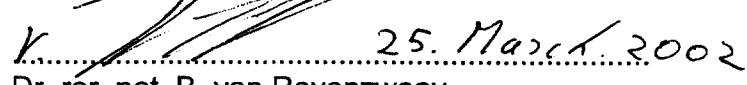
Analysis of inhalation atmosphere:

  
Dr. rer. nat. E. Leibold

Pathology:

  
Dr. med. vet. W. Kaufmann

Management:

  
Dr. rer. nat. B. van Ravenzwaay

**STATEMENT****of the Quality Assurance Unit**

The Quality Assurance Unit (QAU) inspected the study and reported any inspection results to the Study Director and to Management.

The final report reflects the raw data.

Phase of study	Date of inspection (mm-dd-yyyy)	Reported to Study Director and to Management (mm-dd-yyyy)
Study Plan:	02-21-2001	02-21-2001
Conduct of study:	03-16-2001 04-04-2001 05-30-2001 06-21-2001 06-29-2001 09-27-2001	03-16-2001 04-04-2001 05-30-2001 06-21-2001 06-29-2001 09-27-2001
Report:	02-14-2002	02-14-2002

Ludwigshafen, 27 March 2002

  
Zachmann

**STATEMENT OF GLP COMPLIANCE FROM THE COMPETENT AUTHORITY****RheinlandPfalz -**

**Landesanstalt  
für Pflanzenbau und Pflanzenschutz**

**GLP-Bescheinigung / Statement of GLP Compliance**

(gemäß / according to § 19 b Abs. 1 Chemikallengesetz)

Eine GLP-Inspektion zur Überwachung der Einhaltung der GLP-Grundsätze gemäß Chemikallengesetz bzw. Richtlinie 88/320/EG wurde durchgeführt in:

Assessment of conformity with GLP according to Chemikallengesetz and Directive 88/320/EEC at:

Prüfeinrichtung / Test facility  Prüfstandort / Test site

**BASF Aktiengesellschaft  
Experimentelle Toxikologie und Ökologie  
D-67056 Ludwigshafen**

Prüfungen nach Kategorien / Areas of Expertise  
(gemäß/according ChemVwV-GLP Nr. 5.3/OECD guidance)

.....1,2,3,4,5,8,9.....

Datum der Inspektion / Date of Inspection

.....15.05.2001 und vom 21. bis 26.06.2001.....

Die/Der genannte Prüfeinrichtung/Prüfstandort befindet sich im nationalen GLP-Überwachungsverfahren und wird regelmäßig auf Einhaltung der GLP-Grundsätze überwacht.

Auf der Grundlage des Inspektionsberichtes wird hiermit bestätigt, dass in dieser Prüfeinrichtung/diesem Prüfstandort die oben genannten Prüfungen unter Einhaltung der GLP-Grundsätze durchgeführt werden können.

The above mentioned test facility/test site is included in the national GLP-Compliance Programme and is inspected on a regular basis.

Based on the inspection report it can be confirmed, that this test facility/test site is able to conduct the aforementioned studies in compliance with the Principles of GLP.

Unterschrift, Datum / Signature, Date

(Name und Funktion der verantwortlichen Person /  
Name and function of responsible person)

Landesanstalt für Pflanzenbau und Pflanzenschutz, Eschenheimer Str. 144, D-55128 Mainz



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**This report consists of Volume I, II and III.**

## 1. SUMMARY

### Scope of examinations

The present study was performed in order to elucidate the dose response curve of laryngeal findings at low concentrations of Diethanolamine as a follow up of a 90-day inhalation study (Proj. No.: 50I0075/93011) sponsored by BG-Chemie, Heidelberg, Germany.

Male and female Wistar rats were head-nose exposed to dynamic atmospheres of Diethanolamine liquid aerosol / vapor mixtures for 6 hours per working day for about 3 month (65 exposures). The target concentrations were 1.5, 3 and 8 mg/m<sup>3</sup>. Animals exposed to clean air were used as controls.

The following test groups and treatment regimens were used:

Test group	Exposure [mg/m <sup>3</sup> ]	Male animals	Female animals	Recovery period
0	conditioned air	10	10	no
1	1.5	10	10	no
2	3	10	10	no
3	8	10	10	no
0.1	conditioned air	-	10	3 months
2.1	3	-	10	3 months
3.1	8	-	10	3 months

The concentrations of the inhalation atmospheres were analyzed by spectrophotometry of Biuret treated absorption samples in all test groups including control.

Daily means were calculated based on 2 measured samples per concentration and exposure and one measured sample per week in the control group. From the daily mean values of each concentration, mean concentrations and standard deviations for the entire study were derived.

The constancy of concentrations in each inhalation system (except the control system) was continuously monitored by scattered light photometers.

Particle size distributions were determined by cascade impactor measurements.

The general state of health was controlled twice on workdays and once on weekends or holidays. On exposure days clinical observation was performed before, during and after exposure. During the chamber adaptation (preflow) period and on post exposure days clinical findings were recorded once each working day. Body weight of the animals was determined weekly, as a rule.

A complete necropsy including weighing of selected organs and gross pathological evaluation was performed.

Histopathology of the nasal cavity (4 levels), larynx (3 levels), trachea, lung, mediastinal lymph node, liver and gross lesions was performed.

## Results

The following study means of concentrations and particle size distributions were determined analytically:

Test group	Treatment Target concentration (mg/m <sup>3</sup> )	Measured concentration Mean ± SD (mg/kg)	Particle size distribution Mean MMAD (μm) / GSD
0	0 (conditioned air)	0	n.a.
1	1.5	1.57 ± 0.33	0.6 / 3.3
2	3	3.43 ± 0.80	0.6 / 2.8
3	8	8.18 ± 1.45	0.7 / 2.5

MMAD = mass median aerodynamic diameter      n.a. = not applicable  
 GSD = geometric standard deviation

According to the available data on vapor pressure, a considerable part of the low concentration was expected to consist of vapor. This could not be verified during the cascade impactor particle size measurements, as even in the low exposure level the test substance concentration was present in total as deposit on the impactor stages.

No substance related clinical findings were observed. The body weight development of treated and control animals was comparable.

Substance related pathological findings were confined to the larynx, in which squamous metaplasia and inflammatory cell infiltration at the base of the epiglottis was observed at the high concentration (8 mg/m<sup>3</sup>). This change is considered to be an adverse effect due to the concurrence of epithelial change and inflammatory response. However it is considered to be borderline because it showed full reversibility during the 3-month recovery period.

The intermediate concentration (3 mg/m<sup>3</sup>) led to a reversible focal squamous metaplasia at the base of the epiglottis without inflammation in a minority of male animals (3 of 10) examined at the end of the exposure period. This change is considered to represent an adaptive response, rather than a frank adverse effect.

No substance related histopathology was present at the low concentration (1.5 mg/m<sup>3</sup>)

## Conclusion

In the present study, 90-day inhalation exposure of rats to Diethanolamine aerosols resulted in a Low Observed Adverse Effect Concentration (LOAEC) for upper respiratory tract irritation in form of squamous metaplasia of the laryngeal epithelium at the base of the epiglottis accompanied by some inflammatory cell infiltration at the concentration of 8 mg/m<sup>3</sup>. These findings are considered to represent a borderline adverse effect and were fully reversible within the 3-month recovery period. No changes were observed in the nasal cavity or the lower respiratory tract at this concentration.

The No Observed Adverse Effect Concentration (NOAEC) was found to be 3 mg/m<sup>3</sup>.

## 2. INTRODUCTION AND CONCENTRATION SELECTION

### 2.1. AIM OF THE STUDY

In a previous subchronic inhalation study, besides systemic toxicity, a concentration dependent increase in incidence and severity of inflammation in larynx and trachea was observed after exposure to liquid aerosols of Diethanolamine (DEA) at concentrations of 400 and 150 mg/m<sup>3</sup>. Squamous metaplasia and hyperplasia of laryngeal epithelium was additionally present at these exposure levels. Squamous metaplasia and some inflammation was also present in the larynx at the low concentration of 15 mg/m<sup>3</sup> used in the study. Thus an No Observed Adverse Effect Level (NOAEL) was not obtained.

The present investigation was performed to reproduce the upper respiratory tract (URT) findings of the former study and determine a NOAEL for URT effects.

### 2.2. SELECTION OF CONCENTRATIONS

8 mg/m <sup>3</sup>	as high concentration
3 mg/m <sup>3</sup>	as mid concentration
1.5 mg/m <sup>3</sup> (0.35 ppm <sup>1</sup> )	as low concentration

At these low concentrations, which had to be selected considering the aim of the study, the low but finite vapor pressure of DEA may gain importance. The vapor pressure at 20°C as extrapolated from the vapor pressure curve is  $3.744 \times 10^{-4}$  hPa. The estimated saturated vapor concentration of DEA at room temperature from this vapor pressure is about 1.6 mg/m<sup>3</sup>. This means that at the selected lowest exposure level of the study it was expected that a considerable amount of the DEA concentration would have consisted of the vapor.

### 2.3. TEST GUIDELINES

The conduct of inhalation exposures was performed according to the following test guidelines concerning repeated dose inhalation toxicity studies:

- Organization for Economic Cooperation and Development (OECD), OECD Guidelines for Testing of Chemicals, Section 4: No. 413 "Sub-Chronic Inhalation Toxicity: 90-day Study" adopted May 12, 1981.
- Commission Directive 87/302/EEC, "Sub-Chronic Inhalation Toxicity Study", published in the Official Journal of the European Communities L133, May 30 1988.
- US Environmental Protection Agency (EPA), Health Effects Test Guidelines OPPTS 870.3465, 90-Day Inhalation Toxicity, EPA Document 712-C-98-204, August 1998

The examination of the animals was carried out according to the aim of the study.

<sup>1</sup> 1 mg/m<sup>3</sup> ≈ 0.23 ppm at room temperature and atmospheric pressure and assuming 100% evaporation

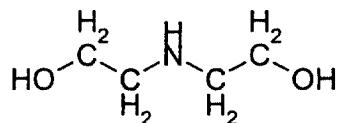
### 3. MATERIAL AND METHODS

#### 3.1. TEST SUBSTANCE

Designation of test substance: Diethanolamine

Chemical name: 2,2'-Iminobisethanol

Structural formula:



CAS No.: 111-42-2

Supplier: The Dow Chemical Company

Batch No.: OG1701A9U1

Date of production: not known

Test substance No.: 99/299-2

Degree of purity prior to the study (characterization): 99.89%

Homogeneity: homogeneous

Stability: The stability of the test substance over the study period was taken for granted on the basis of analytical results with a comparable batch.

Aggregate state/appearance: Liquid / colorless, clear

Storage conditions: Room temperature, blanketed with Nitrogen

More details of the test substance can be found in Volume III of this report.  
The analyses were delivered by the supplier.

### **3.2. TEST ANIMALS**

#### **3.2.1. Species and strain**

Male and female Wistar rats (strain: CrIGlxBrlHan:WI) were supplied by Charles River Deutschland GmbH, Sandhofer Weg 7, 97633 Sulzfeld.

The female animals were nulliparous and non-pregnant.

Only animals free from clinical signs of disease were used for the study.

#### **3.2.2. Animal identification**

The animals were identified individually by tattooing the respective animal number into the ears.

#### **3.2.3. Reasons for species selection**

This species and strain was also used in the preceding inhalation studies.

### **3.3. HOUSING AND DIET**

During the period when the rats were not exposed they were housed singly in makrolon-wire cages (type MD III, Becker & Co., Castrop-Rauxel, FRG (floor area about 800 cm<sup>2</sup>)). Underneath the cages, waste trays were fixed containing bedding material (type 3/4 dust free embedding, supplied by SSNIFF, Soest, FRG).

The animals were kept in fully air-conditioned rooms in which a temperature in the range of 20 - 24°C and relative humidity in the range of 30 - 70% were ensured by means of a central air-conditioning system.

A light/dark rhythm of 12 hours was maintained:

- 06.00 a.m. - 06.00 p.m. light
- 06.00 p.m. - 06.00 a.m. dark

Deviations from these ranges did not occur.

The room was completely disinfected using a disinfecter ("AUTEX", fully automatic, formalin-ammonia-based terminal disinfecter, supplied by Dr. Gruß KG, Neuss, FRG) before the start of the study. Usually, each week the floor and the walls were cleaned with water containing about 1 % Mikroquat®.

The animals were maintained on rat/mouse/hamster laboratory diet, 10 mm pellets (Provimi Kliba SA, Kaiseraugst, Switzerland) and tap water ad libitum.

During exposure food and water were withdrawn.

Details of the feed batch used are available in the raw data.

### 3.4. TEST GROUPS AND TARGET CONCENTRATIONS

Test groups, target concentrations and allocation of animals in the groups are presented in the following tables.

#### Main groups

##### Male animals

Test group	Color code	Concentration (mg/m <sup>3</sup> )	No. of animals	Animal No.
0	grey	0	10	1-10
1	blue	1.5	10	11-20
2	yellow	3	10	21-30
3	red	8	10	31-40

##### Female animals

Test group	Color code	Concentration (mg/m <sup>3</sup> )	No. of animals	Animal No.
0	grey	0	10	41-50
1	blue	1.5	10	51-60
2	yellow	3	10	61-70
3	red	8	10	71-80

In the pathology the test group numbers are indicated by the prefix F1.

#### Recovery groups (examination after about 3 month post exposure observation period)

##### Female animals

Test group	Color code	Concentration (mg/m <sup>3</sup> )	No. of animals	Animal No.
0.1	grey	0	10	81-90 <sup>1</sup>
2.1	yellow	3	10	91-100
3.1	red	8	10	101-110

In the pathology the test group numbers are indicated by the prefix R1 and the numbers 0, 2 - 3.

<sup>1</sup> As Animal No. 88 died incidentally on study day 14 it was substituted with an animal from the same delivery. Thus, body weight and clinical data for this animal are only available starting with study day 14.

### 3.5. ANALYSES

#### 3.5.1. Calculation of nominal concentrations

The nominal concentration was not determined because in aerosol studies, especially where equipment for concentration dilution and reduction of particle size is used, the nominal concentration is not comparable and of no significance to the analytically measured one. The efficiency of the generation system was not of importance as well in this study.

#### 3.5.2. Analytical determination of concentrations

Principle:

The concentrations of the inhalation atmospheres were analyzed by spectrophotometry after derivatisation with Biuret reagent.

Daily means were calculated based on 2 measured samples per concentration and exposure in the treatment groups (test groups 1-3). From the daily mean values of each concentration, mean concentrations and standard deviations for the entire study were derived.

In these groups, the constancy of concentrations in each inhalation system was continuously monitored by scattered light photometers.

One sample per week was gathered and analyzed in the control group (test group 0).

##### 3.5.2.1. Sampling for spectrophotometric analyses

Equipment:

- Sampling probe (glass) with quartz wool plug, internal diameter 7 mm
- 3 absorption vessels (glass)<sup>1</sup>
- Absorption solvent : doubly distilled water
- Sampling station GS 312 (DESAGA)

Sampling:

- Sampling velocity: 1.25 m/s
- Flow rate of sampling: 3 l/min
- Sample volumes:
  - Test group 0 100 l
  - Test group 1 400 l
  - Test group 2 200 l
  - Test group 3 100 l
- The sample volumes were adjusted to achieve amounts of test substance in the samples within the calibration range of the analytical method (see below).
- Sampling site: immediately adjacent to the animals' noses
- Sampling frequency: as a rule, 2 samples per concentration and exposure.

<sup>1</sup> No quartz wool plug and only one absorption vessel was used for the control group.

The samples were drawn through the 3 absorption vessels connected in series, each of which was filled with doubly distilled water as absorption solvent. After each sampling, the content of the probe with quartz wool plug and the first 2 absorption vessels was eluted and pooled into a 50 ml graduated flask for individual analysis.

After the final sampling for each exposure, the content of the last absorption vessel was transferred to a 50 ml graduated flask and analyzed separately to check for the absorbing efficiency of sampling.

### **3.5.2.2. Spectrophotometric analyses**

Equipment:

Spectrophotometer DM4

Calibration of the method:

Method set up:

During the set up of the analytical procedure a calibration curve was prepared in the solvent with the test substance to show linearity in the suitable concentration range of the samples.

The method was calibrated by means of calibration solutions in doubly distilled water. Accurately weighed amounts in a concentration ranges of 0.22 to 1.10 mg/50 ml were used for this purpose. A calibration curve was calculated (curve adjusted using the least squares method) showing linear correlation (Details of the method are archived with the raw data).

Routine analysis during test period:

A calibration curve of the analytical procedure was prepared for each analytical campaign based on the method described above (details are available in the raw data).

Treatment and analyses of samples:

One part (v/v) of Biuret reagent was added to three parts of filtered sample.

The pretreated samples were measured against a 1 + 3 dilution of the Biuret reagent in doubly distilled water as the blank value in 5 cm cuvettes at a wavelength of 650 nm. The concentrations were determined from the measured data according to volumes and calibration curve values, which were determined before each measuring campaign.

**Limit of Quantification (LoQ):**

From the variation of the daily calibration curves an LoQ of the method of about 0.070 OD corresponding to 0.2 mg/50ml and to a concentration of 0.5 mg/m<sup>3</sup> for the sample volume of test group 1 (biggest sampling volume used) was estimated. Concentration values below the LoQ are reported as 0.

**3.5.2.3. Real time monitoring of constancy of concentrations**

Scattered light photometers (RAM1 [Mie, USA] in test groups 1 and 2 and SAD1 [Hund, Germany] in test group 3) were used to continuously monitor the constancy of concentrations of test substance aerosols in the inhalation systems. To this end the inhalation atmosphere was continuously sampled the measuring devices. The measurements were recorded using line recorders (see examples in figure 003 in the APPENDIX) and transferred to the automated measuring system (results are presented in the table IC - 001in the Appendix ar tables IIC in Volume II)

**3.5.3. Particle size analysis****3.5.3.1. Definitions**

- EACD 50%(effective aerodynamic cutoff diameter 50%) defines the separation characteristic of each impactor stage. 50% of particles with the EACD given are deposited in the pertinent impactor stage; the remainder has reached one of the following stages.
- MMAD(mass median aerodynamic diameter) is the calculated aerodynamic diameter which divides the size distribution in half when measured by mass.
- Geometrical standard deviation (GSD) is the ratio of the estimated 84 percentile to the 50 percentile and indicates the slope of the cumulative particle size distribution curve.
- **Inspirable aerosol**

Inspirable aerosols can enter the respiratory system. The MAK list 1996 of the DFG (German Research Society) defines the particle size distribution for inspirable particles in humans. According to this, aerosols with MMADs < 100 µm are considered inspirable

- **Respirable aerosol**

Respirable aerosols can enter the alveolar region of the lung. The MAK list 1996 of the DFG (German Research Society) defines the particle size distribution for respirable particles in humans. According to this, aerosols with MMADs ≤ 4 µm are considered respirable.

### **3.5.3.2. Equipment, sampling and method of determination**

The particle size analysis was carried out with cascade impactors.

Equipment for particle size analysis:

- Stack sampler Marple 298 (Sierra)
- Vacuum compressed air pump (Millipore)
- Limiting orifice 3 l/min (Millipore)
- Sampling probe internal diameter 7 mm
- 2 absorption vessels connected in series with the impactor
- Absorption solvent : doubly distilled water

Sampling for particle size analyses:

Metal collecting discs and a backup particle filter were placed into the cascade impactor and samples were taken in each concentration at a sampling velocity of 1.25 m/sec from the breathing zones of the animals according to the following table.

Table 3.5.3.2.: Sample numbers and volumes

Test group	Number of samples	Sample Volume (l)
1	8	720
2	6	360
3	6	180

Method of analysis:

The metal collecting discs and the backup particle filter were eluted individually with doubly distilled water into graduated flasks, filled up to the calibration mark and analyzed as described earlier in this section

The deposits in the probe and the wall losses in the impactor were also determined by eluting the respective parts of the impactor and analysis as described above.

The content of the absorption vessels was analyzed in order to get information of the amount of test substance eventually evaporating from the impactor.

Evaluation:

The calculation of the particle size distribution was carried out in the Experimental Toxicology and Ecology of BASF Aktiengesellschaft on the basis of mathematical methods for evaluating particle measurements (DIN 66141: Darstellung von Korngrößenverteilungen and DIN 66161: Partikelgrößenanalyse, Beuth-Vertrieb GmbH, Berlin und Köln, FRG).

### **3.5.4. Food analyses**

The food used in the study was assayed for chemical as well as for microbiological contaminants.

### 3.5.5. Drinking water analyses

The drinking water is regularly assayed for chemical contaminants by the municipal authorities of Frankenthal, FRG and the Technical Services of BASF Aktiengesellschaft as well as for the presence of microorganisms by a contract laboratory.

## 3.6. EXPERIMENTAL PROCEDURE

### 3.6.1. Acclimatization and exposure period

The animals were delivered on March 6, 2001 at an age of about 7 weeks and subjected immediately to the acclimatization period in which they were adapted to the surroundings.

The animals were allocated to the test groups strictly at random. The purpose of this was to obtain test groups of equal weight.

At the start of the exposure period (day 0) the overall mean body weight calculated from the group means and the ranges of individual weights () were:

- |                                   |                         |
|-----------------------------------|-------------------------|
| • male animals, main groups       | 225.7 (205.3 – 245.8) g |
| • female animals, main groups     | 166.2 (153.2 – 175.7) g |
| • female animals, recovery groups | 166.7 (154.1 – 182.1) g |

#### 3.6.1.1. Time schedule

The study was performed according to the following time table:

Table 3.6.1.1.:

Date		Study day		Action
male	female	male	female	
March 6, 2001	March 6, 2001	-10	-13	Arrival of the animals Start of the experimental phase of the study
March 13, 2001	March 14, 2001	-3	-5	Start of preflow period
March 16, 2001	March 19, 2001	0	0	Start of exposure period
June 27, 2001	June 28, 2001	104	101	End of exposure period = start of recovery period
June 28, 2001	June 29, 2001	105	102	Necropsy of the main groups
	Sept. 27, 2001		192	Necropsy of the recovery groups

End of the experimental phase of the study: Dec. 10, 2001

### 3.6.2. Generation of the inhalation atmospheres

(see schematic figure 001a, APPENDIX)

Generator systems:

- Continuous infusion pumps PERFUSOR (B. Braun)
- Two-component atomizers (stainless steel, Schlick mod. 970)
- Glass mixing stages (BASF)
- Glass dilution tube (BASF)
- Glass cyclonic separators (BASF)
- Thermostat (Haake)

Generation procedure:

For each concentration the test substance was supplied to a two-component atomizer at a constant rate by means of a metering pump. The aerosol was generated with compressed air in a mixing stage mixed with conditioned dilution air and passed via the cyclonic separator and the dilution tube into the inhalation system.

The desired concentrations in test groups 1 - 3 were achieved by substituting appropriate amounts of aerosol (exhaust air 1) by conditioned supply air (supply air 3 in schematic figure 001a).

The control group was exposed to conditioned air.

The following values of test pump rates and air flows were scheduled.

Table 3.6.2.: Scheduled operation conditions

Test group	Pump rate [ml/h]	Supply air 1 conditioned [m <sup>3</sup> /h]	Supply air 2 compressed [m <sup>3</sup> /h]	Supply air 3 conditioned [m <sup>3</sup> /h]	Exhaust air 1 [m <sup>3</sup> /h]	Exhaust air 2 [m <sup>3</sup> /h]
0 / 0.1	-	4.5 ± 0.3	1.5 ± 0.3	-	-	5.4 ± 0.3
1 / 1.1	1 - 2.5	4.5 ± 0.3	1.5 ± 0.3	4 - 6	4 - 6	5.4 ± 0.3
2 / 2.1	1 - 2.5	4.5 ± 0.3	1.5 ± 0.3	4 - 6	4 - 6	5.4 ± 0.3
3 / 3.1	1 - 2.5	4.5 ± 0.3	1.5 ± 0.3	4 - 6	4 - 6	5.4 ± 0.3

m<sup>3</sup>/h = cubicmeter per hour

ml/h = milliliter per hour

Conditioned supply air is activated charcoal filtered air conditioned to about 50% ± 20% relative humidity and 22°C ± 2°C.

Compressed air is activated charcoal filtered air pressurized to about 6 bar.

In order to avoid solidification of the test substance in the delivery systems (pump, tubing and atomizer) of test group 1 - 3, they were thermostated to about 45 – 55°C.

### 3.6.3. Exposure systems; exposure of the animals

#### Head-nose exposure systems

(see schematic figure 001b, APPENDIX)

The inhalation atmosphere was maintained inside aerodynamic exposure systems (INA 60, volume  $V \approx 90$  l, BASF Aktiengesellschaft) consisting of a cylindrical inhalation chamber made of stainless steel sheeting and cone-shaped outlets and inlets. The rats were restrained in glass exposure tubes. Their snouts projected into the inhalation chamber and thus they inhaled the aerosol.

#### Exposures

The head-nose exposure technique was preferably selected for this vapour/aerosol inhalation study to minimize fur contamination of the animals with the substance, which cannot be avoided during whole-body exposure. Fur contamination may lead to an additional dermal and oral uptake (animals preen as their fur becomes contaminated). Thus an estimation of an nominal dose, taken up by the animals and its correlation to a toxic effect becomes more difficult.

Furthermore, by using the dynamic mode of operation with a low-volume chamber, the equilibrium characteristic of this exposure technique is favorable:  $t_{99}$  (the time to reach 99% of the final target concentration) is shorter as compared to whole-body chambers with a higher chamber volume.

A positive pressure was maintained inside the exposure systems by adjusting the air flow of the exhaust air system. This ensured that the aerosol in the breathing zones of the animals was not diluted by laboratory air.

In order to accustom the animals to exposure they were treated with supply air under conditions comparable to exposure on 3 days before start of exposure (preflow period). The all test groups were exposed for 6 hours on each workday over a time period suitable to reach 65 exposures.

The animals did not have access to water or feed during the exposure.

### 3.6.4. Measurements of the exposure conditions

Recording of exposure parameters was performed according to the following table.

Table 3.6.4.: Exposure parameters, methods of determination and recording

Exposure parameters	Determination method	Recording
Supply air 1 (conditioned) in test group 0	orifice plate with differential pressure measurement	automated system
Supply air 1 (conditioned) in test groups 1-3	Rotameter	three times per exposure
Supply air 2 (compressed)	orifice plate with differential pressure measurement	automated system

Supply air 3 (conditioned) test groups 1-3 only	Rotameter	three times per exposure
Exhaust air 1 test groups 1-3 only	Rotameter	three times per exposure
Exhaust air 2	orifice plate with differential pressure measurement	automated system
Atomizer Pressure test groups 1-3 only	manometer	once per exposure
Chamber humidity	Dielectric probe (Vaisala)	automated system
Chamber temperature	Thermosensor	automated system
Generator temperature test groups 1-3 only	Thermosensor	automated system
Pump rate test groups 1-3 only	Reading from pump display	once per exposure

No surveillance of the oxygen content in the inhalation system was performed. The air change within the inhalation systems was judged to be sufficient to prevent oxygen depletion by the breathing of the animals and the concentrations of the test substance used could not have a substantial influence on oxygen partial pressure.

Principles of recording with the automated measuring system:

Each parameter was measured at appropriate measuring points using suitable measuring equipment (sensors, orifice plates etc.). The measurements were standardized (0 - 20 or 4 - 20 mA) and transferred to instrumentation consoles. There, the measured values were displayed in an analogous way (where this is provided for) and some were used as actual value for regulating the specific parameter.

In addition, the measured values were scanned every 10 seconds, converted from analog to digital, transferred to a personal computer, displayed on its screen, and saved on hard disk. The computer checked the arriving values against preset threshold values, displayed warnings if violations of thresholds occurred and recorded the start and the end of threshold violations for each measured parameter affected. After the end of each exposure all data gathered during this exposure were backed up on optical media.

Daily protocols were prepared from the recorded values using suitable software. The protocols include start and stop times of exposure and possible threshold violations, and daily means of each parameter. The records saved on optical media and the printed daily records are considered as raw data. Relevant disturbances are reported under "Results".

### 3.7. CLINICAL EXAMINATIONS

#### 3.7.1. Clinical observations

An observation of the general state of health of the animals as well as a check for dead or moribund animals was performed twice a day on working days or once a day on weekends or public holidays, respectively.

Clinical examinations of the test animals were carried out on workdays at least 3 times on exposure days and, as a rule, once during the preflow period and the post-exposure observation period.

### 3.7.2. Body weight data

The body weight of the animals was determined at the start of the preflow, at the start of the exposure period and then, as a rule, once a week. As a rule, the animals were weighed at the same time of the day.

Body weight change was calculated as the difference between body weight on the respective exposure day and body weight on the day of the first exposure (study day 0)<sup>1</sup>. Group means were derived from the individual differences.

### 3.7.3. Statistics of clinical examinations

Means and standard deviations of each test group were calculated for several parameters (see tables). Further statistical analyses were performed according to following table:

Parameters	Statistical test	Markers in the tables	References
Body weight, body weight change	Parametric one-way analysis using the F-test (ANOVA) (two-sided). If the resulting p-value was equal or less 0.05, a comparison of each group with the control group using the DUNNETT's test (two-sided) was performed for the hypothesis of equal means	* for $p \leq 0.05$ ** for $p \leq 0.01$	WINER, B.J. (1971): Statistical principles in experimental design. McGraw-Hill New York, 2nd edition  DUNNETT, C.W. (1955): A multiple comparison procedure for comparing several treatments with a control. J. Amer. Statistic. Assoc. (JASA), Vol. 50, 1096 - 1121  DUNNETT, C.W. (1964): New tables for multiple comparisons with a control. Biometrics, Vol. 20, 482 - 491

## 3.8. PATHOLOGY

### 3.8.1. Necropsy

The animals were killed under Narcoren® anesthesia by exsanguination from the abdominal aorta and vena cava. The animals were necropsied and assessed by gross pathology.

### 3.8.2. Organ weights

Weight determination was performed according to the listing below:

<sup>1</sup> Body weight change was not calculated for substitute animal no. 88

1. Anesthetised animals
2. Liver
3. Kidneys
4. Adrenal glands
5. Testes
6. Spleen
7. Brain
8. Heart
9. Lungs

### **3.8.3. Organ/ tissue preservation list**

The following organs/ tissues were removed and fixed in 4% formaldehyde solution:

1. All gross lesions
2. Head
3. Larynx
4. Trachea
5. Lungs
6. Mediastinal lymph nodes
7. Liver
8. Kidneys
9. Spleen
10. Adrenal glands
11. Heart
12. Testes
13. Brain

### **3.8.4. Histotechnical processing and light – microscopical examination**

After an appropriate fixation period, organs and tissues were histotechnically processed and light – microscopically examined and assessed according to the tables below:

Table 3.8.4.1: (Main groups)

Organs	Test groups			
	0	1	2	3
Nasal cavity (I – IV)	A1	A1	A1	A1
Larynx (I – III)	A1	A1	A1	A1
Trachea with bifurcation	A1	A1	A1	A1
Lungs	A1			A1
Mediastinal lymph node	A1			A1
Liver	A1			A1
All gross lesions	A2	A2	A2	A2

## METHODS/SCOPE OF EXAMINATIONS:

- A = Hematoxylin – Eosin  
1 = All test animals per group  
2 = All affected test animals per group

Table 3.8.4.2: (Recovery groups)

Organs	Test groups			
	0.1		2.1	3.1
Nasal cavity (I – IV)	A1			A1
Larynx (I – III)	A1			A1
All gross lesions	A2		A2	A2

## METHODS/SCOPE OF EXAMINATIONS:

- A = Hematoxylin – Eosin  
1 = All test animals per group  
2 = All affected test animals per group

### 3.8.5. Statistics of pathology

Means and standard deviations of each test group were calculated for the variables of terminal body weight and of absolute and relative organ weights (related to terminal body weight) of the animals in each test group. Further statistical analyses were performed according to table 3 below:

Table 3.8.5:

Parameters	Statistical test	Markers in the tables	References
Weight parameters	Non-parametric one-way analysis using KRUSKAL-WALLIS test (two-sided). If the resulting p-value was equal or less than 0.05, a pairwise comparison of each dose group with the control group was performed using the WILCOXON test for the hypothesis of equal medians	* for $p \leq 0.05$  ** for $p \leq 0.01$	HETTMANNSPERGER, T.P. (1984): Statistical Inference based on Ranks, John Wiley & Sons New York, 132-140.  International Mathematical and Statistical Libraries, Inc., 2500 Park West Tower One, Houston, Texas 77042-3020, USA, nakl-1 - nakl-3  MILLER, R.G. (1981): Simultaneous Statistical Inference Springer-Verlag New York Inc., 165-167  NIJENHUIS, A. and S.W. WILF (1978): Combinatorial Algorithms, Academic Press, New York, 32-33

### 3.9. RETENTION OF RECORDS

GLP – relevant records and materials are stored at BASF Aktiengesellschaft for at least the period of time specified in the GLP principles. Details concerning responsibilities or locations of archiving can be seen from the respective SOPs and from the raw data.

The retention of the analytical raw data are in the responsibility of the sponsor.

## 4. RESULTS AND ASSESSMENT OF FINDINGS

### 4.1. ANALYSES

#### 4.1.1. Measurements of atmosphere parameters and operation conditions

Detailed results of the measurements of concentrations, operation conditions and particle size analyses can be found in the APPENDIX of Volume I and in Part C of Volume II.

Individual values may be found in the record sheets and are kept with the raw data.

##### 4.1.1.1. Concentration measurements in the exposure system

(Figures 002 and 003; Tables IC-001, IIC-001 - IIC-004)

Table 4.1.1.1.: Study means and standard deviations of test substance concentrations

Test group	Target concentration (mg/m <sup>3</sup> )	Measured concentration (mg/m <sup>3</sup> )	
		Mean	SD
0	0	0	0
1	1.5	1.57	0.33
2	3	3.43	0.80
3	8	8.18	1.45

Real time surveillance of the inhalation atmospheres with scattered light photometers generally proved the constancy of each concentration throughout the daily exposures. Examples of recorder protocols are depicted in figure 003 in the Appendix (original protocols are archived with the raw data).

There was some scatter of the daily concentrations around the mean values (figure 002 in the Appendix), although the operation conditions were kept as constant as possible. This scatter is reflected in the standard deviations of the study means, which were in the range of 20% of the mean.

##### 4.1.1.2. Measurements concerning operation conditions

(Tables IC-001, IIC-001 - IIC-004)

The air flows were constantly maintained in the desired range. An air change of about 67 times per hour can be calculated by dividing the supply air flow through the volume of the inhalation system.

Mean relative humidities in the inhalation systems ranged between 41.3 and 47.1%. Mean temperatures in the inhalation systems ranged between 22.6 and 23.3°C.

#### **4.1.1.3. Results of the particle size analyses**

(Tables IC-002 – IC004, IIC-005 - IIC-24)

All measurements of particle size resulted in MMADs below 0.9 µm with GSDs around 3.

The mean MMADs were 0.6, 0.6 and 0.7 for test group 1, 2 and 3, respectively.

Thus the aerosols were highly respirable for rats.

#### **4.1.2. Food analyses**

On the basis of duration of use and the analytical findings with respect to chemical and microbiological contaminants the feed was found to be suitable. Fed. Reg. Vol. 44, No. 91 of May 09, 1979, p. 27354 (EPA), served as a guideline for maximum tolerable chemical contaminants. The amount of germs did not exceed  $10^5$ /g feed.

Individual results can be found in the archives of the Experimental Toxicology and Ecology of BASF Aktiengesellschaft.

#### **4.1.3. Drinking water analyses**

On the basis of the analytical findings the drinking water was found to be suitable. German Drinking Water Regulation (Trinkwasserverordnung, Bundesgesetzblatt, Dec. 05, 1990) served as a guideline for maximum tolerable contaminants.

Individual results can be found in the archives of the Experimental Toxicology and Ecology of BASF Aktiengesellschaft.

### **4.2. CLINICAL EXAMINATIONS**

Summary Tables of the results can be found in the APPENDIX of Volume I (Tables IA-1 – IA-36); individual values are to be found in Part A of Volume II (Tables IIA-1 - IIA-31)

#### **4.2.1. Mortality**

One female animal of the recovery control group (test group 0.1, animal no.: 86) died during the exposure period (study day 22)<sup>1</sup>. One female animal of the high recovery group (test group 3.1, animal no.: 107) died during the recovery period (study day 147).

These deaths are considered to be incidental. No special cause of death could be established during necropsy.

<sup>1</sup> Another female animal (no. 88) which died early during the study was substituted with an animal of the same delivery (see also section „Material and Methods“)

**4.2.2. Clinical observations**

(Summary tables IA-1 - IA-14 in the APPENDIX and individual value tables IIA-1 - IIA-23 in Volume II)

No substance related clinical signs or findings were observed during the preflow, the exposure and the post-exposure observation period.

Alopecia was observed in few, skin lesions, decubitus, yellow discoloration of fur, red crust formation of the nose, dark crust formation of nose margin, reduced general condition, reduced care on fur, piloerection and an enlarged testes in single animals. These findings are considered to be incidental.

**4.2.3. Body weight data**

(Figures Nos. 004a – 004c, Summary tables IA-15 - IA-36 in the APPENDIX and Individual values tables IIA-24 - IIA-31 in Volume II)

Body weight:

The mean body weights of the test substance exposed main and recovery groups was not statistically significantly different from the respective control group.

Body weight change:

The mean body weight change of the male main group animals were not statistically significantly different from the respective control groups.

The mean body weight change of the female main group animals showed statistically significant decreases in test group 1 ( $1.5 \text{ mg/m}^3$ ) on study days 73, 80 and 86 and in test group 2 ( $3 \text{ mg/m}^3$ ) on study days 45, 59 and 73.

As no decrease in body weight change was observed in test group 3 ( $8 \text{ mg/m}^3$ ) the decreases in test groups 1 and 2 are interpreted as incidental.

**4.2.4. Assessment of Clinical Observations**

*Clinical observations:*

All changes observed are not considered to be substance related.

## 4.3. PATHOLOGY

### 4.3.1. Weight parameters

(Tables IC 1 – IC 6)

When inter group differences are referred to as "significant", it implies that the differences have attained statistical significance ( $p \leq 0.05$ ) when compared with the control group.

#### 4.3.1.1. Absolute weights

Main groups:

There was a significant increase of liver (+12%), lungs (+10%) and kidney weights (+6%) in high test group females. In concentration group 2, a significant slight decrease of liver weights (-7%) was noted.

Recovery groups:

There were no significant weight changes noted.

#### 4.3.1.2. Relative weights

Main groups:

There was a significant increase of liver weights (+14%) in high concentration test group females.

Recovery groups:

There were no significant weight changes noted.

### 4.3.2. Gross lesions

(Tables IC 7 – IC 8)

Liver

A "focal constriction" was noted in one female of group 2 as well as a "focus" in one group 1 and one group 2 male. In the recovery groups, a "cyst" and a "focus" were found in two different group 2 females.

Kidneys

A "retraction" was recorded in one group 2 male. In the recovery groups, a "granular surface" was described for one group 3 female.

**Testes**

A "focus" was present in one male of group 1 and one male of group 2. The "organ size was reduced" in one male of group 1 and one male of group 3.

**Epididymides**

An "abscess" was noted in one group 1 male and the epididymides appeared "enlarged" in one group 3 male.

**Ovaries**

A "cyst" was recorded in one group 1 female.

**Uterus**

A "dilation" was present in one group 3 female.

**Pituitary gland**

A "cyst" was found in one group 3 female.

**Skin**

A "decubitus" was noted in one group 1 female. "Sparse hair" was recorded for one group 2 male and one control and one group 3 female. In the recovery groups, one group 2 female showed "sparse hair" as well.

**Lungs**

In the recovery groups, an "atelectasis" was recorded for one group 3 female and a "discoloration" for one female control.

**Liver lymph node**

In the recovery groups, a "discoloration" was present in one group 2 female.

**4.3.3. Histopathology**

(Tables IC 9 – IC 12)

**Nasal cavity**

Main and recovery groups:

There were no substance – induced lesions detected.

**Larynx****Main groups:**

A focal squamous metaplasia was recognized at the base of epiglottis (primarily level I, ventral laryngeal epithelium) in 9 male and 9 female test animals of the high concentration group. In addition, inflammatory cell infiltrates were found in 3 out of 10 males and females of the same concentration group. In the concentration group 2, the finding of a focal squamous metaplasia was still observed in 3 out of 10 male test animals.

The focal squamous metaplasia of the laryngeal epithelium and the slightly increased occurrence of inflammatory cells in the underlying layer are seen to be treatment – related effects.

**Recovery groups:**

There were no substance – induced lesions detected.

**Trachea**

There were no substance – induced lesions detected.

**Lungs**

There were no substance – induced lesions detected.

**Mediastinal lymph node**

There were no substance – induced lesions detected.

**Liver**

There were no substance – induced lesions detected.

## 5. DISCUSSION AND CONCLUSIONS

The desired target concentrations were achieved with some scatter around the overall study mean value of each concentration. The coefficient of variance was about 20 % for each exposure concentration. Although the atmosphere generation parameters were kept as constant as possible, the complexity of the generation system for producing this kind of low concentrations (comprising low pump rates, warming of the test material from syringe via tubing to the atomizer for lowering viscosity and extracting considerable amounts of the primary aerosol for replacing it by clean air in order to dilute the concentrations to the target levels) offers enough variability to explain this scatter.

In spite of the variation, the overall course of daily concentrations allows for clear discrimination between the different concentration.

The particle size measurements revealed rat respirable aerosols in all test substance atmospheres including the low concentration. Under the conditions of this study evaporation of the test substance as was expected from the information on vapor pressure was not observed. From the results of particle size measurements and the readings of the scattered light photometers, it is concluded, that even in the low concentration the major fraction, if not all, of the concentration was present as aerosol.

As expected from the preceding 90-day study (BG Chemie, 1996) no substance related clinical findings occurred.

The slight but statistically significant organ weight changes observed during macroscopic pathology (increase of the absolute liver, kidney and lung weights in high concentration main group females, decrease of absolute liver weight in mid concentration main group females and increase of relative liver weights in high concentration main group females) are considered to be incidental and of no biological relevance due to the following reasons:

- The changes were isolated findings in the female main groups and neither observed in males nor in the recovery groups
- The increased absolute lung and kidney weights in the high concentration females and decreased absolute liver weights in the mid concentration females were not accompanied by corresponding changes in of relative weights.
- There were no histopathological correlates explaining the weight changes.
- No organ weight changes were observed in the preceding 90-day study (BG Chemie, 1996) at 15 mg/m<sup>3</sup>

Histopathology of three levels of the larynx reproduced lesions in the high concentration group (8 mg/m<sup>3</sup>) which were already reported as treatment – related effects in the low concentration group (15 mg/m<sup>3</sup>) of the preceding study. Male and female test animals showed a focal squamous metaplasia of the laryngeal epithelium and an inflammatory reaction in a few cases as well. The combined occurrence of epithelial change and inflammation is considered to represent an adverse effect.

In the intermediate concentration groups of this study (3 mg/m<sup>3</sup>) three of the male main group animals (3/10) developed a focal squamous metaplasia but no inflammatory cell reaction was visible any longer. The focal squamous metaplasia of the laryngeal epithelium

without inflammatory cell infiltration is interpreted as adaptive change (Burger G.T. et al. (1989) caused by the inhalation of the compound, rather than a true adverse effect. No lesions on the larynx were observed in the low concentration groups ( $1,5 \text{ mg/m}^3$ ).

Neither the nasal cavity, nor trachea or lungs exhibited any substance – induced histomorphological changes at the concentrations used in this study.

After a recovery period of three months, no treatment – related histomorphological lesions were found in the larynx of the examined high concentration group ( $8 \text{ mg/m}^3$ ). This shows that the observed changes on the laryngeal epithelium were reversible during this time.

Thus, the 3 – month inhalation exposure of Wistar rats to Diethanolamine aerosols led to the following, substance – related adverse effects:

High concentration ( $8 \text{ mg/m}^3$ ):

Larynx:

- Focal squamous metaplasia (ventral laryngeal epithelium, at the base of epiglottis) in male (9/10) and female (9/10) test animals accompanied by a
- Higher incidence and slightly higher gradings of inflammatory cell infiltrates in male (3/10) and female (3/10) test animals when compared with the control (2/10 or 1/10)

Medium ( $3 \text{ mg/m}^3$ ) and low concentration ( $1,5 \text{ mg/m}^3$ ):

No substance – related adverse effects detected.

No substance – related findings were found after the 3 – month recovery period. Thus, full reversibility of the changes observed directly after the exposure period was present including the lesions caused by the high concentration, which are considered to represent borderline adverse effects.

## Conclusion

In the present study, 90-day inhalation exposure of rats to Diethanolamine aerosols resulted in a Low Observed Adverse Effect Concentration (LOAEC) for upper respiratory tract irritation in form of squamous metaplasia of the laryngeal epithelium at the base of the epiglottis accompanied by some inflammatory cell infiltration at the concentration of  $8 \text{ mg/m}^3$ . These findings are considered to represent a borderline adverse effect and were fully reversible within the 3-month recovery period. No changes were observed in the nasal cavity or the lower respiratory tract at this concentration.

The No Observed Adverse Effect Concentration (NOAEC) was found to be  $3 \text{ mg/m}^3$ .

## 6. REFERENCES

BG Chemie, Diethanolamin – Subchronic inhalation and neurotoxicity study in Wistar rats, 90-day liquid aerosol exposure, BG-No.: 158, BASF Proj. No.: 50I0075/93001, unpublished report 1996

Burger G.T., Renne R.A., Sagartz J.W., Ayres P.H., Coggins C.R.E., Mosberg A.T., and Hayes A.W. (1989). Histologic changes in the respiratory tract induced by inhalation of xenobiotics: physiologic adaptation or toxicity. *Toxicol.Appl.Pharmacol.* **101**, 521-542.

## 7. APPENDIX (FIGURES AND SUMMARY TABLES)

### 7.1. LIST OF THE ABBREVIATIONS USED IN TABLES IA

%	= per cent
g	= gram
SD	= standard deviation
N, n	= number of animals
mg/m <sup>3</sup>	= milligram per cubicmeter
BW Change	= body weight change
*	= significance level
NC	= not calculate

### 7.2. LIST OF THE ABBREVIATIONS USED IN TABLES IB

F	= female animals
F1	= final sacrifice groups
g	= weight determination in grams
R1	= recovery group
M	= male animals (under sex); mean value (on weight level)
mg	= weight determination in milligrams
mg/m <sup>3</sup>	= milligram per cubicmeter
n	= number of values measured for the determination of mean value and standard deviation
NAD	= number of animals without gross lesions
SD	= standard deviation
%	= percentage related to the reference weight in relative organ weight calculations

#### Codes for the status at necropsy:

- 1 = planned sacrifice
- 2 = killed moribund
- 3 = intercurrent death

#### Codes used at finding level:

The codes are used for a grading system which takes into consideration either the severity or the number or the size of a microscopic finding.

	<b>Severity</b>	<b>Number</b>	<b>Size</b>
Grade 1	Minimal	Very few	Very small
Grade 2	Slight	Few	Small
Grade 3	Moderate	Moderate number; several	Moderate size
Grade 4	Marked; severe	Many	Large
Grade 5	Massive; extreme	Extensive number	Extensive size

Whenever a grading was not used, the microscopic finding was indicated to be present (P).

### 7.3. LIST OF THE ABBREVIATIONS USED IN TABLES IC

%	= per cent
ml/h	= milliliter per hour
m <sup>3</sup> /h	= Cubic meter per hour
mg/m <sup>3</sup>	= milligram per cubic meter
mg	= milligram
SD	= standard deviation
°C	= degree Celsius
%RH	= per cent relative humidity
-	= not calculate
MMAD	= mass median aerodynamic diameter 50%
µm	= micrometer
GSD	= Geometrical standard deviation
Impg., Imp.	= Impinger
Conc.	= concentration
Anal.	= analytical

For calculating the average MMAD for each concentration group, the measurements from which no MMAD could reasonably be derived were set to the value of 0.4 µm. This is considered to be an acceptable approach because the particle size distributions of these measurements represent a median particle size well below 0.4 µm. Not taking them into account would have resulted in a higher mean MMAD as actually achieved.

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Figure 001a: Technical assembly

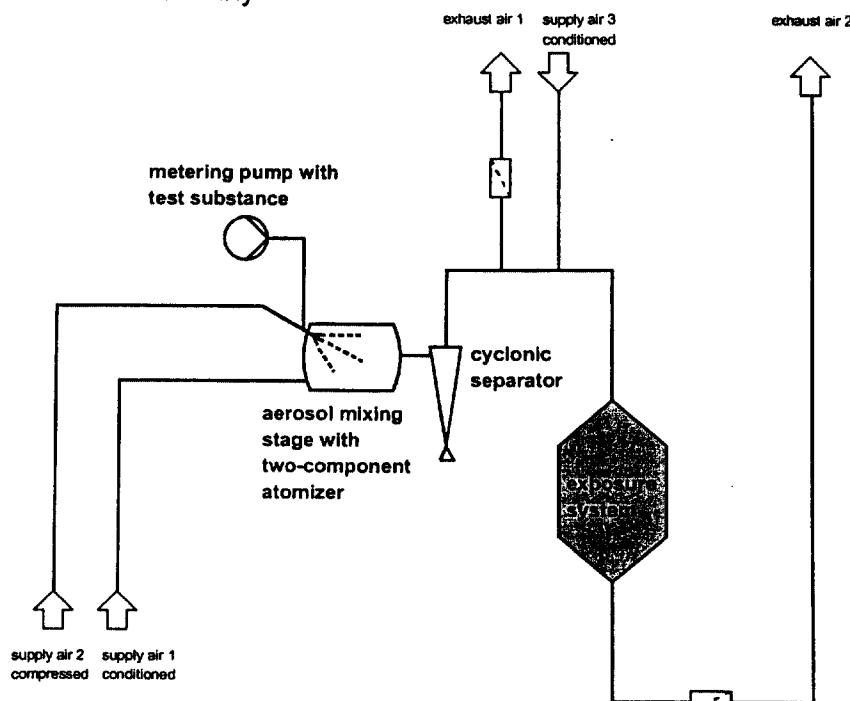
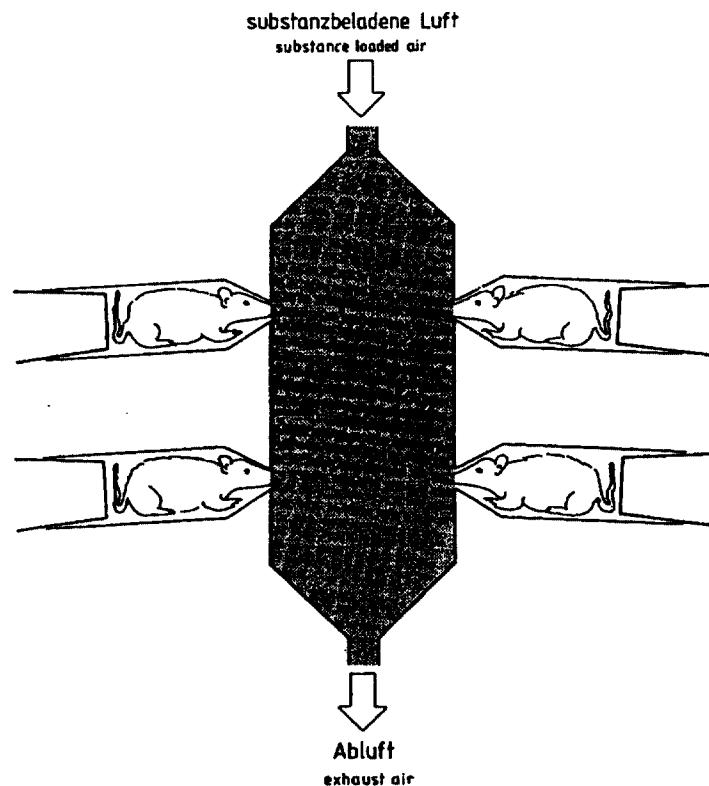
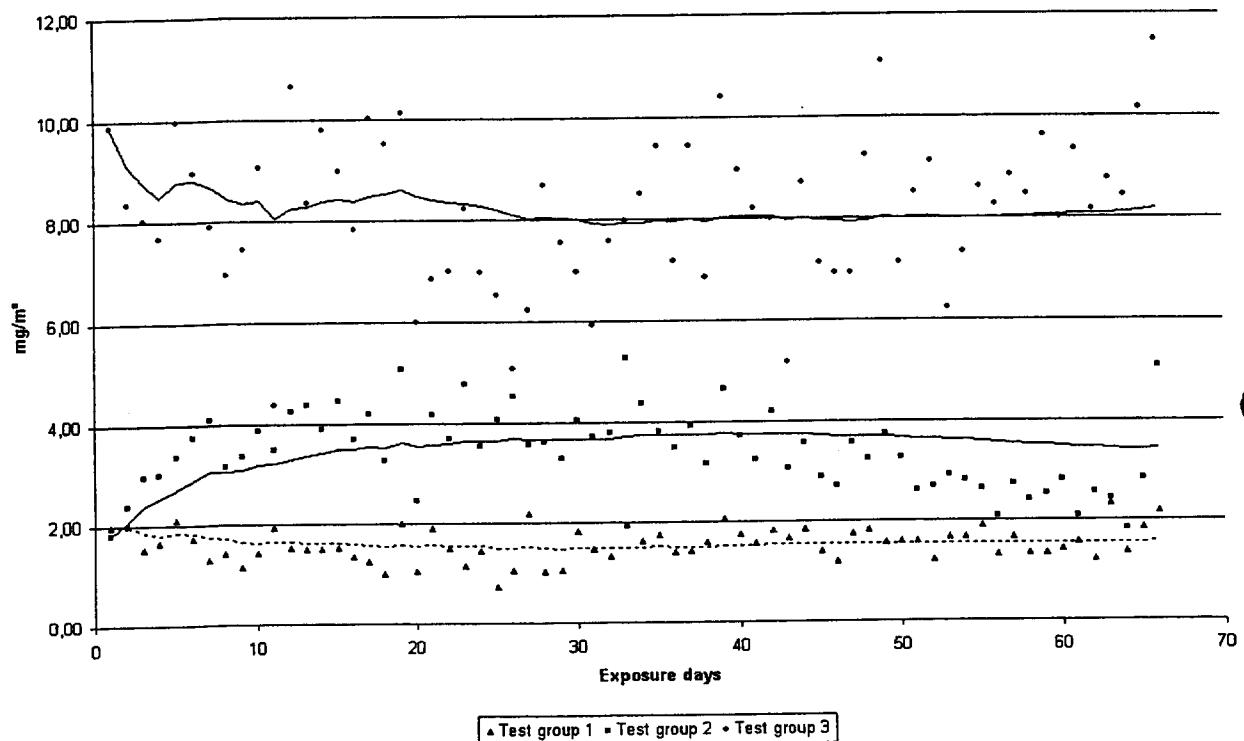


Figure 001b: Exposure systems



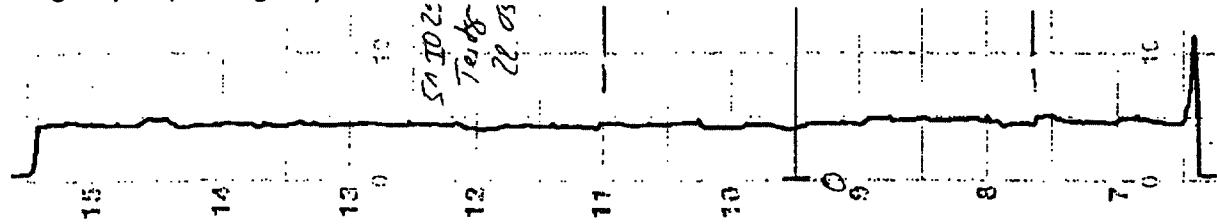
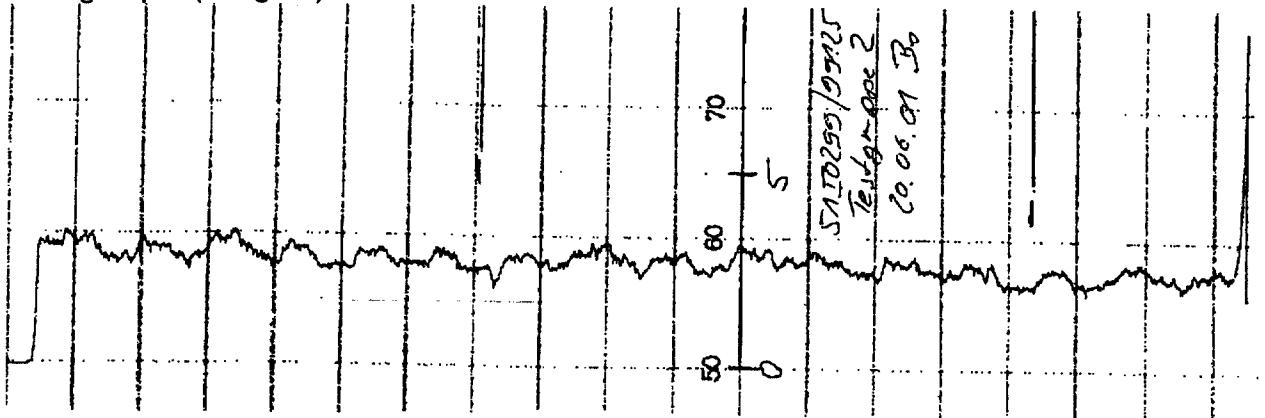
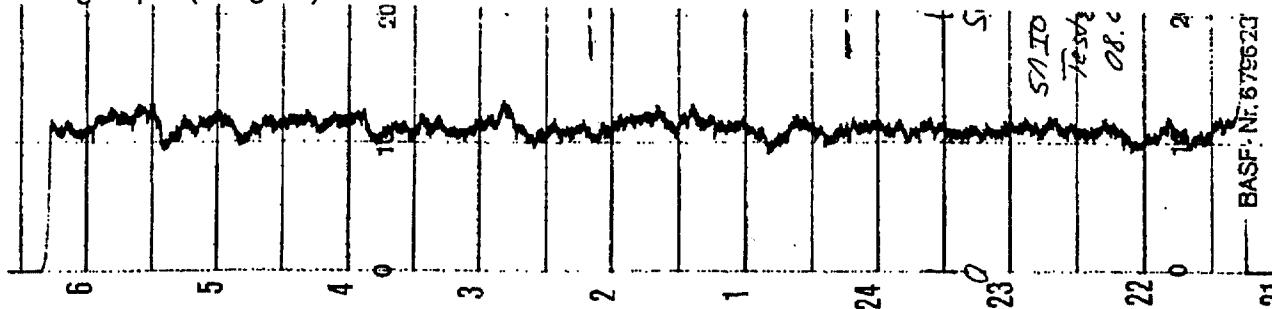
Report; Project No.: 51I0299/99125

Figure 002: Time course of daily concentrations



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Figure 003: Examples of concentration real time records

Test group 1 (1.5 mg/m<sup>3</sup>)Test group 2 (3 mg/m<sup>3</sup>)Test group 3 (8 mg/m<sup>3</sup>)

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Figure 004a: Body weight development of male main group animals

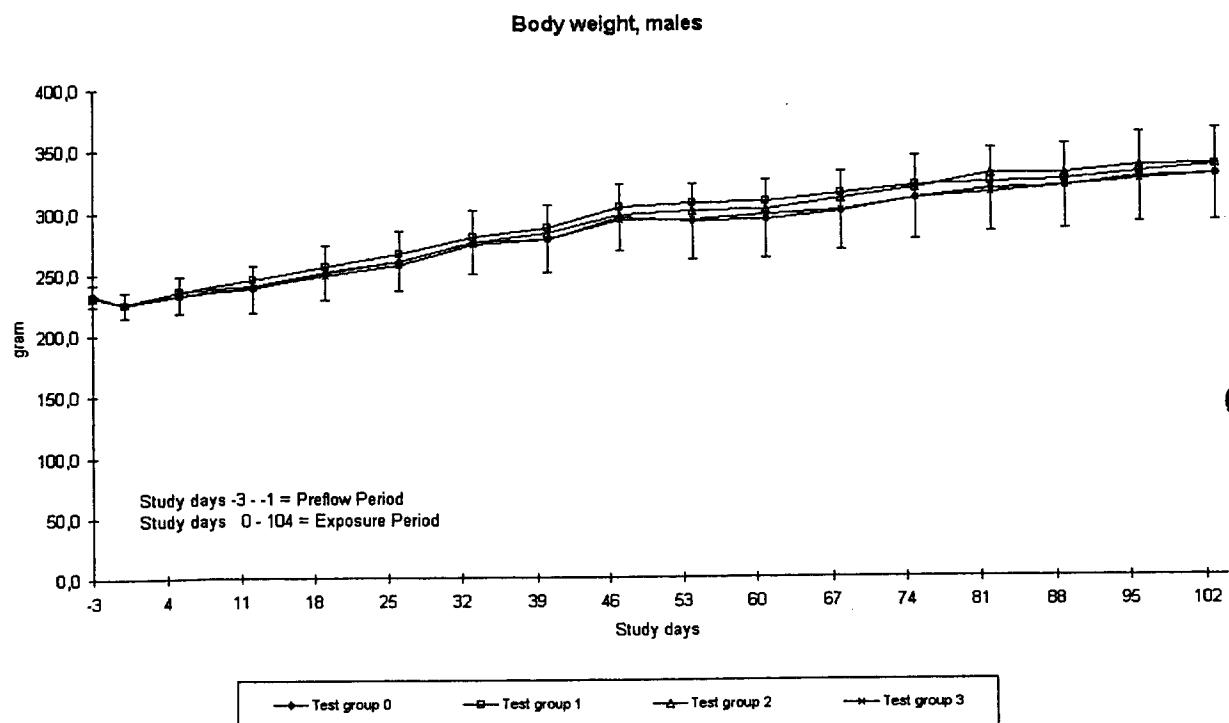
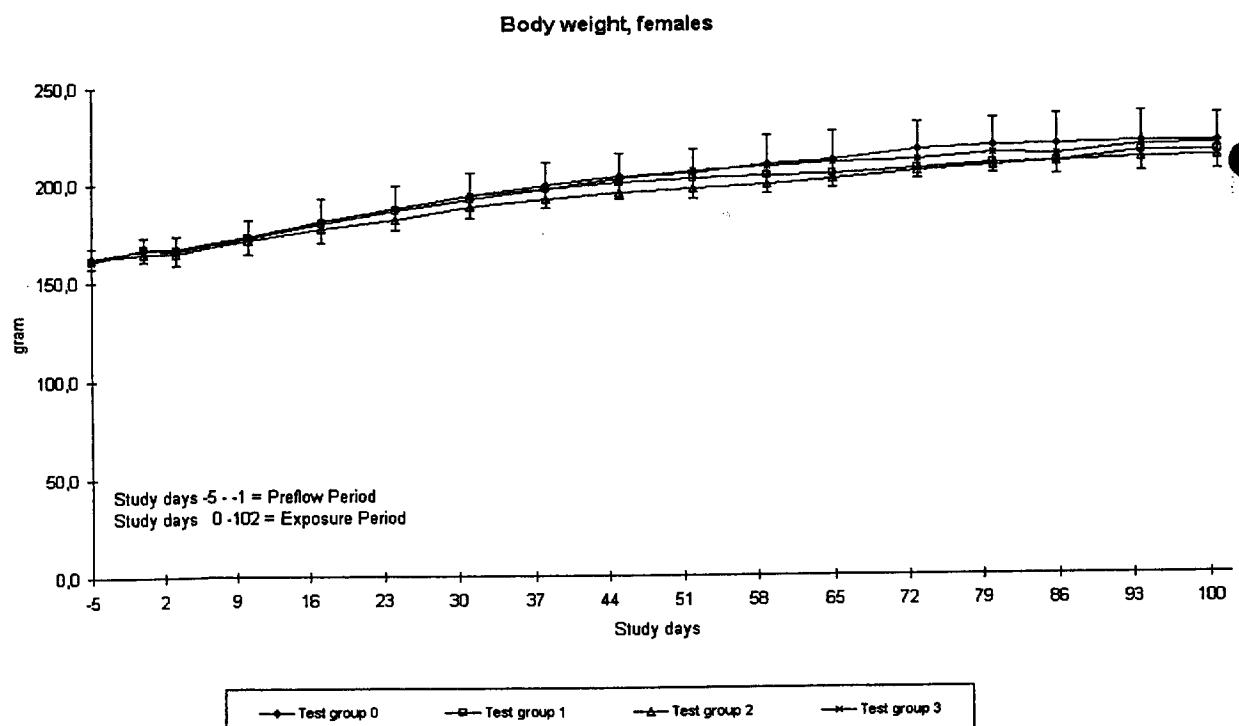
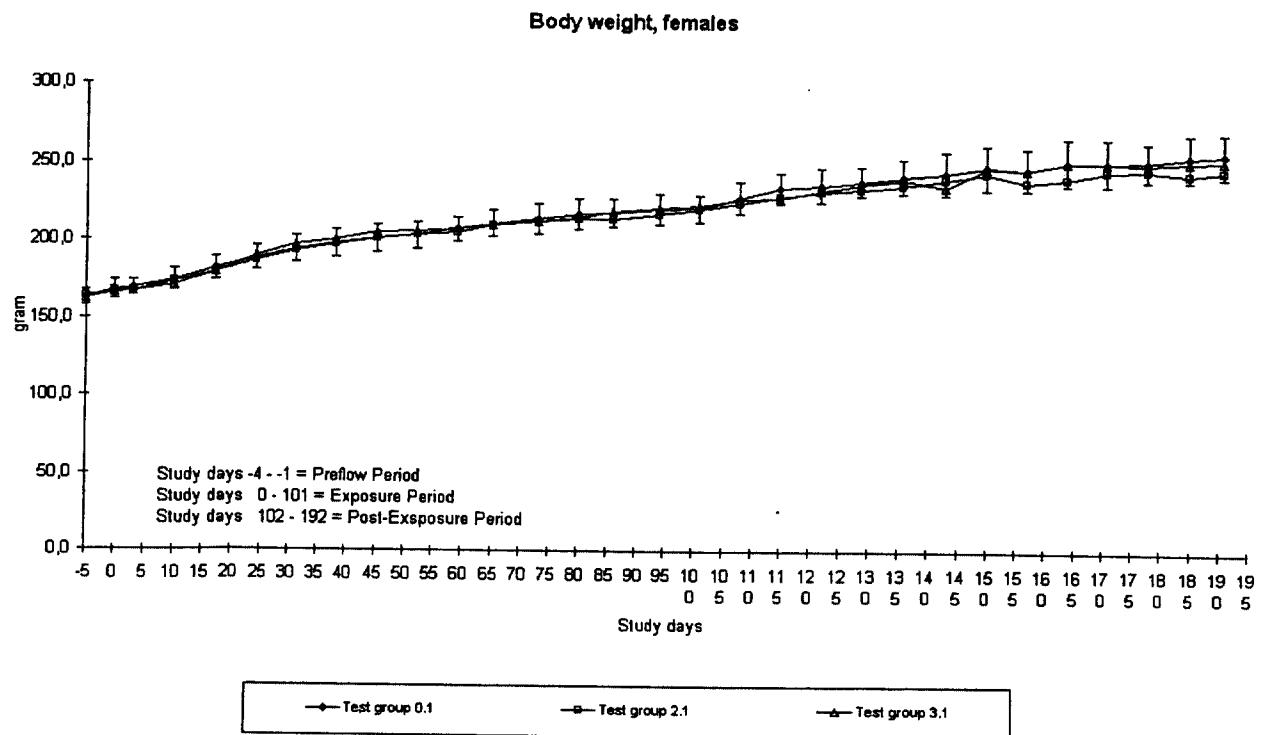


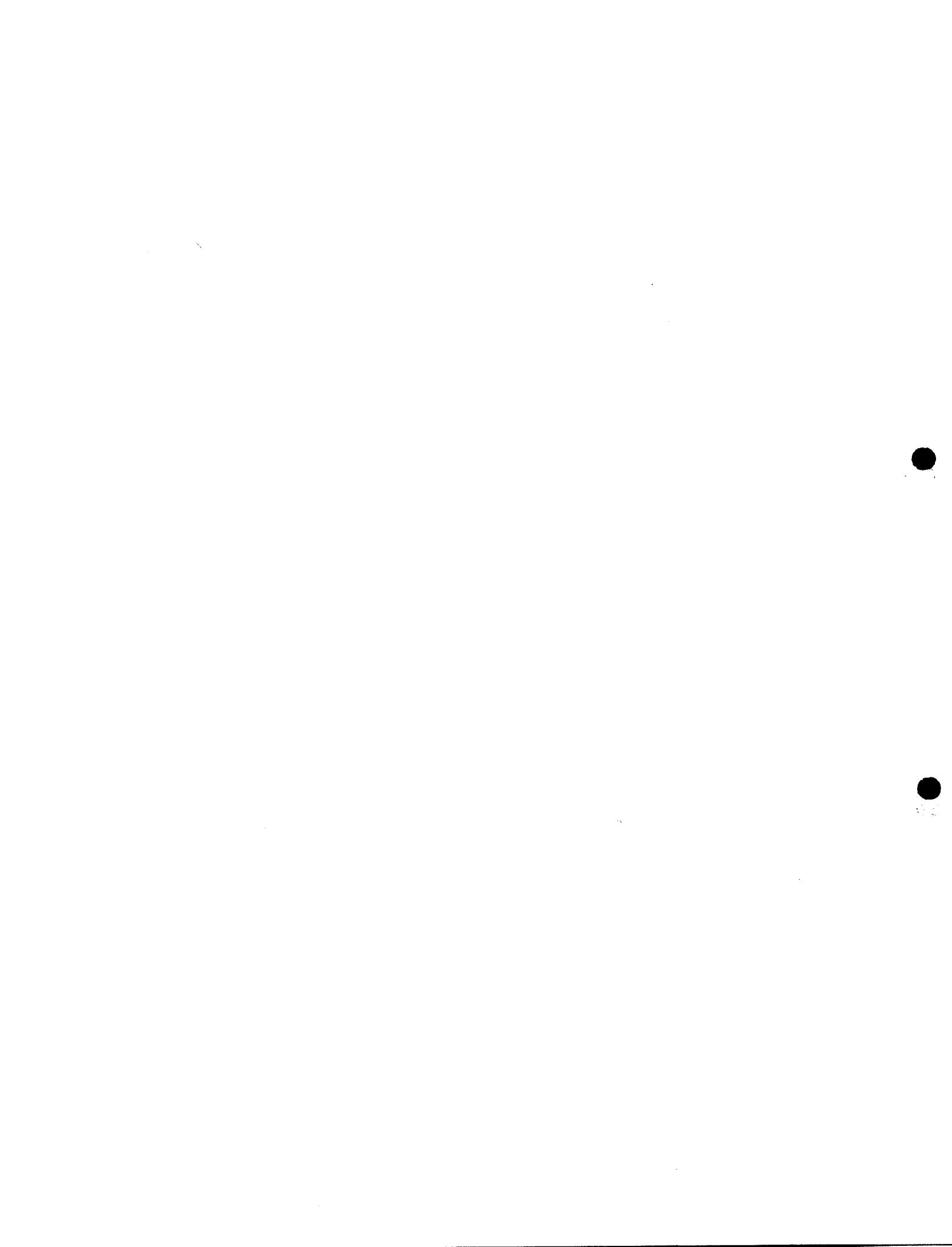
Figure 004b: Body weight development of female main group animals



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Figure 004c: Body weight development of male recovery group animals





BASF - DATATOX-F1 R11

Study: 5110299/99125  
Sex: Male

Treatment Group	0 Gr 0 0 mg/m <sup>3</sup>	1 Gr 1 1.5 mg/m <sup>3</sup>	2 Gr 2 3 mg/m <sup>3</sup>	3 Gr 3 8 mg/m <sup>3</sup>
Animal Count	10	10	10	10
General observation				
Nothing abnormal detected				
Incidence	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Observed	30	30	30	30
Mean onset (Days)	-3	-3	-3	-3
TOTALS				
Incidence	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Observed	30	30	30	30
Mean onset (Days)	-3	-3	-3	-3

OBSERVATIONS REPORT - INCIDENCE

Print Date: 05-Nov-2001  
Print Time: 14:36:13  
Table : 1A  
Page : 1

BASF - DATATOX-F1 R11

Study: 5110299/99125  
Sex: Female

Treatment Group      0      Gr 0 0 mg/m\*3  
Dose      10  
Animal Count

General observation  
Nothing abnormal detected

Incidence      10 (100%)  
Observed      30  
Mean onset (Days)      -5

TOTALS

Incidence      10 (100%)  
Observed      30  
Mean onset (Days)      -5

OBSERVATIONS REPORT - INCIDENCE

Print Date: 05-Nov-2001  
Print Time: 14:36:13  
Table : 1A  
Page : 2

Study: 5110299/99125  
 Sex: Male

Treatment Group  
 Dose  
 Animal Count

0  
 Gr 0 0 mg/m<sup>3</sup>  
 10

General observation  
 Nothing abnormal detected

	Incidence Observed	Mean onset (Days)	
Incidence	10 (100%)	1950	10 (100%)
Observed	0	0	1893
Mean onset (Days)			0

TOTALS

	Incidence Observed	Mean onset (Days)	
Incidence	10 (100%)	1950	10 (100%)
Observed	0	0	1893
Mean onset (Days)			0

Testis  
 enlarged  
 left

	Incidence Observed	Mean onset (Days)	
Incidence	1 ( 10%)	57	1 ( 10%)
Observed	0	74	57
Mean onset (Days)			74

TOTALS

	Incidence Observed	Mean onset (Days)	
Incidence	1 ( 10%)	57	0 ( 0%)
Observed	0	74	0
Mean onset (Days)			57

Alopecia  
 body

	Incidence Observed	Mean onset (Days)	
Incidence	1 ( 10%)	165	1 ( 10%)
Observed	0	14	0
Mean onset (Days)			165

TOTALS

## OBSERVATIONS REPORT - INCIDENCE

Print Date: 05-Nov-2001  
 Print Time: 14:49:38  
 Table : IA  
 Page : 3

## OBSERVATIONS REPORT - INCIDENCE

Study: 5110299/99125  
Sex: Female

Treatment Group	0 Gr 0 0 mg/m <sup>3</sup>	1 Gr 1 1.5 mg/m <sup>3</sup>	2 Gr 2 3 mg/m <sup>3</sup>	3 Gr 3 8 mg/m <sup>3</sup>
Dose	10	10	10	10
Animal Count	0	0	0	0
General observation				
Nothing abnormal detected				
Incidence	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Observed	1782	1890	1950	1842
Mean onset (Days)	0	0	0	0
TOTALS				
Incidence	10 (100%)	10 (100%)	10 (100%)	10 (100%)
Observed	1782	1890	1950	1842
Mean onset (Days)	0	0	0	0
Decubitus				
hind limb				
right				
Incidence	1 ( 10%)	1 ( 10%)	0 ( 0%)	0 ( 0%)
Observed	36	36	0	0
Mean onset (Days)	84	84	0	0
TOTALS				
Incidence	0 ( 0%)	1 ( 10%)	0 ( 0%)	0 ( 0%)
Observed	0	36	0	0
Mean onset (Days)	0	84	0	0
Alopecia				
body				
Incidence	1 ( 10%)	1 ( 10%)	0 ( 0%)	1 ( 10%)
Observed	124	124	0	108
Mean onset (Days)	35	35	0	45
TOTALS				
Incidence	1 ( 10%)	1 ( 10%)	0 ( 0%)	1 ( 10%)
Observed	124	124	0	108
Mean onset (Days)	35	35	0	45
Skin lesion				
Incidence	1 ( 10%)	0 ( 0%)	0 ( 0%)	1 ( 10%)
Observed	60	0	0	11
Mean onset (Days)	11	0	0	45

BASF - DATATOX-F1 R11

Study: 51I0299/99125  
Sex: Female

Treatment Group Dose Animal Count	0 Gr 0 0 mg/m <sup>3</sup> 10	1 Gr 1 1.5 mg/m <sup>3</sup> 10	2 Gr 2 3 mg/m <sup>3</sup> 10	3 Gr 3 8 mg/m <sup>3</sup> 10
<b>TOTALS</b>				
Incidence Observed Mean onset (Days)	1 ( 10%) 60 11	0 ( 0%) 0	0 ( 0%) 0	0 ( 0%) 0
Fur discoloration yellow				
Incidence Observed Mean onset (Days)	1 ( 10%) 24 92			

Incidenc  
Observed  
Mean onset (Days)

Fur  
discoloration  
yellow

Treatment Group Dose Animal Count	0 Gr 0 0 mg/m <sup>3</sup> 10	1 Gr 1 1.5 mg/m <sup>3</sup> 10	2 Gr 2 3 mg/m <sup>3</sup> 10	3 Gr 3 8 mg/m <sup>3</sup> 10
<b>TOTALS</b>				
Incidence Observed Mean onset (Days)	0 ( 0%) 0	1 ( 10%) 24	0 ( 0%) 0	0 ( 0%) 0

Incidenc  
Observed  
Mean onset (Days)

Print Date: 05-Nov-2001  
Print Time: 14:50:58  
Table : 1A  
Page : 5

OBSERVATIONS REPORT - INCIDENCE

## OBSERVATIONS REPORT - INCIDENCE

Print Date: 05-Nov-2001  
 Print Time: 14:53:23  
 Table : 1A  
 Page : 6

	Treatment Group	0 Gr 0 0 mg/m*3	1 Gr 1 1.5 mg/m*3	2 Gr 2 3 mg/m*3	3 Gr 3 8 mg/m*3
	Dose	10	10	10	10
General observation	Nothing abnormal detected				
	Incidence	10 (100%)	9 ( 90%)	9 ( 90%)	10 (100%)
	Observed	10	9	9	10
	Mean onset (Days)	104	104	104	104
TOTALS					
	Incidence	10 (100%)	9 ( 90%)	9 ( 90%)	10 (100%)
	Observed	10	9	9	10
	Mean onset (Days)	104	104	104	104
Sacrificed scheduled					
	Incidence	10 (100%)	10 (100%)	10 (100%)	10 (100%)
	Observed	10	10	10	10
	Mean onset (Days)	104	104	104	104
TOTALS					
	Incidence	10 (100%)	10 (100%)	10 (100%)	10 (100%)
	Observed	10	10	10	10
	Mean onset (Days)	104	104	104	104
Testis enlarged left					
	Incidence		1 ( 10%)		
	Observed		1		
	Mean onset (Days)		104		
TOTALS					
	Incidence	0 ( 0%)	1 ( 10%)	0 ( 0%)	0 ( 0%)
	Observed	0	1	0	0
	Mean onset (Days)		104		
Alopecia body					
	Incidence				
	Observed				
	Mean onset (Days)				

BASF - DATATOX-F1 R11

Study: 5110299/99125  
Sex: Male

Treatment Group	Dose	Incidence	Observed	Mean onset (Days)
0	Gr 0 0 mg/m <sup>3</sup>	0 ( 0%)	0	
10	Gr 1 1.5 mg/m <sup>3</sup>	0 ( 0%)	0	
	Gr 2 3 mg/m <sup>3</sup>	1 ( 10%)	1	
	Gr 3 8 mg/m <sup>3</sup>	0 ( 0%)	0	
	10		104	

OBSERVATIONS REPORT - INCIDENCE

Print Date: 05-Nov-2001  
Print Time: 14:53:23  
Table : 1A  
Page : 7

Study: 5110299/99125  
Sex: Female

Treatment Group      0 Gr 0 0 mg/m<sup>3</sup>  
Dose                    10  
Animal Count          10

General observation  
Nothing abnormal detected

Incidence	9 ( 90%)
Observed	9
Mean onset (Days)	102

TOTALS

Incidence	9 ( 90%)
Observed	9
Mean onset (Days)	102

Sacrificed scheduled

Incidence	10 (100%)
Observed	10
Mean onset (Days)	102

TOTALS

Incidence	10 (100%)
Observed	10
Mean onset (Days)	102

Decubitus  
hind limb  
right

Incidence	1 ( 10%)
Observed	1
Mean onset (Days)	102

TOTALS

Incidence	1 ( 10%)
Observed	1
Mean onset (Days)	102

Alopecia  
body

Incidence	1 ( 10%)
Observed	1
Mean onset (Days)	102

OBSERVATIONS REPORT - INCIDENCE

Print Date: 05-Nov-2001  
Print Time: 14:55:31  
Table : 1A  
Page : 8

3  
Gr 3 8 mg/m<sup>3</sup>  
10

2  
Gr 2 3 mg/m<sup>3</sup>  
10

1  
Gr 1 1.5 mg/m<sup>3</sup>  
10

8 ( 80%)  
8  
102

8 ( 80%)  
8  
102

8 ( 80%)  
8  
102

10 (100%)  
10  
102

10 (100%)  
10  
102

9 ( 90%)  
9  
102

9 ( 90%)  
9  
102

1 ( 10%)  
1  
102

BASF - DATA0X-F1 R11

Study: 5110299/99125

Sex: Female

Print Date: 05-Nov-2001  
Print Time: 14:55:31  
Table : 1A  
Page : 9

OBSERVATIONS REPORT - INCIDENCE

Treatment Group	Dose	Incidence Observed	Mean onset (Days)	Gr 0 0 mg/m*3	Gr 1 1.5 mg/m*3	Gr 2 3 mg/m*3	Gr 3 8 mg/m*3
TOTALS				0	10	10	10
Fur discoloration yellow							
TOTALS							

Incidence  
Observed  
Mean onset (Days)

Incidence  
Observed  
Mean onset (Days)

BASF - DATATOX-F1 R11

Study: 5110299/99125

Sex: Female

Treatment Group  
Dose  
Animal Count

01  
Gr 01 0 mg/m<sup>3</sup>  
10

General observation  
Nothing abnormal detected

Incidence  
Observed  
Mean onset (Days)

9 ( 90%)  
27  
-5

TOTALS

Incidence  
Observed  
Mean onset (Days)

9 ( 90%)  
27  
-5

#### OBSERVATIONS REPORT - INCIDENCE

Print Date: 08-Nov-2001  
Print Time: 11:19:16  
Table : IA  
Page : 10

01  
Gr 21 3 mg/m<sup>3</sup>  
10

Incidence  
Observed  
Mean onset (Days)

10 (100%)  
30  
-5

Incidence  
Observed  
Mean onset (Days)

10 (100%)  
30  
-5

Incidence  
Observed  
Mean onset (Days)

10 (100%)  
30  
-5

31  
Gr 31 8 mg/m<sup>3</sup>  
10

Study: 5110299/991125  
Sex: Female

Treatment Group  
Dose  
Animal Count

Treatment Group	01
Dose	Gr 01 0 mg/m <sup>3</sup>
Animal Count	10

General observation  
Nothing abnormal detected

Incidence	10	(100%)
Observed	1772	
Mean onset (Days)	2	

TOTALS

Incidence	10	(100%)
Observed	1772	
Mean onset (Days)	2	

TOTALS

Incidence	1	( 10%)
Observed	1	
Mean onset (Days)	22	

TOTALS

Incidence	1	( 10%)
Observed	1	
Mean onset (Days)	22	

Nose, crust formation  
red  
moderate

Incidence	1	( 10%)
Observed	1	
Mean onset (Days)	22	

TOTALS

Incidence	1	( 10%)
Observed	1	
Mean onset (Days)	22	

TOTALS

TOTALS

#### OBSERVATIONS REPORT - INCIDENCE

Print Date: 08-Nov-2001  
Print Time: 12:08:16  
Table : IA  
Page : 11

Treatment Group	21
Dose	Gr 21 3 mg/m <sup>3</sup>
Animal Count	10

Incidence	31
Observed	Gr 31 8 mg/m <sup>3</sup>
Mean onset (Days)	10

Incidence	10	(100%)
Observed	1950	
Mean onset (Days)	0	

Incidence	10	(100%)
Observed	1950	
Mean onset (Days)	0	

Incidence	1	( 10%)
Observed	1	
Mean onset (Days)	22	

TOTALS

Incidence	10	(100%)
Observed	1950	
Mean onset (Days)	0	

TOTALS

TOTALS

Study: 5110299/99125  
Sex: FemaleTreatment Group  
Dose  
Animal Count01  
Gr 01 0 mg/m<sup>3</sup>  
10General observation  
Nothing abnormal detectedIncidence  
Observed  
Mean onset (Days)  
TOTALS9 ( 90%)  
585  
102

TOTALS

Sacrificed scheduled  
Incidence  
Observed  
Mean onset (Days)9 ( 90%)  
585  
102

TOTALS

Incidence  
Observed  
Mean onset (Days)9 ( 90%)  
9  
192

TOTALS

Found dead  
Incidence  
Observed  
Mean onset (Days)9 ( 90%)  
9  
192

TOTALS

Incidence  
Observed  
Mean onset (Days)1 ( 10%)  
1  
147

TOTALS

Reduced general condition  
moderate  
Incidence  
Observed  
Mean onset (Days)0 ( 0%)  
0  
147

TOTALS

Incidence  
Observed  
Mean onset (Days)1 ( 10%)  
1  
143

TOTALS

Incidence  
Observed  
Mean onset (Days)1 ( 10%)  
2  
143

## OBSERVATIONS REPORT - INCIDENCE

Print Date: 08-Nov-2001  
Print Time: 12:20:48  
Table : IA  
Page : 12

Study: 5110299/991125  
Sex: Female

Treatment Group  
Dose  
Animal Count

01  
Gr 01 0 mg/m<sup>3</sup>  
10

Nose, margin, crust formation  
dark  
moderate

Incidence  
Observed  
Mean onset (Days)

TOTALS

Incidence  
Observed  
Mean onset (Days)

Reduced care on fur

Incidence  
Observed  
Mean onset (Days)

TOTALS

Incidence  
Observed  
Mean onset (Days)

Piloerection

Incidence  
Observed  
Mean onset (Days)

TOTALS

Incidence  
Observed  
Mean onset (Days)

Alopecia  
limbs  
hind limb  
left

Incidence  
Observed  
Mean onset (Days)

#### OBSERVATIONS REPORT - INCIDENCE

Print Date: 08-Nov-2001  
Print Time: 12:20:48  
Table : IA  
Page : 13

21  
Gr 21 3 mg/m<sup>3</sup>  
10

31  
Gr 31 8 mg/m<sup>3</sup>  
10

1 ( 10%)  
2  
143

1 ( 10%)  
2  
143

1 ( 10%)  
2  
143

1 ( 10%)  
2  
143

1 ( 10%)  
2  
143

1 ( 10%)  
39  
140

BASF - DATAT0X-F1 R11

Print Date: 08-Nov-2001  
Print Time: 12:20:48  
Table : IA  
Page : 14

OBSERVATIONS REPORT - INCIDENCE

Study: 5110299/99125  
Sex: Female

Treatment Group	01 Gr 01 0 mg/m <sup>3</sup>	21 Gr 21 3 mg/m <sup>3</sup>	31 Gr 31 8 mg/m <sup>3</sup>
Dose	10	10	10
Animal Count			
<b>TOTALS</b>			
Incidence	0 ( 0%)	1 ( 10%)	0 ( 0%)
Observed	0	39	0
Mean onset (Days)	140		

## BODY WEIGHT

	Body Weight g Day -3 0	Body Weight g Day 0 0	Body Weight g Day 5 0	Body Weight g Day 12 0	Body Weight g Day 19 0	Body Weight g Day 26 0	Body Weight g Day 33 0	Body Weight g Day 40 0
<b>Male, Gr 0 0 mg/m³</b>								
Mean	232.7	224.9	232.5	237.1	249.9	259.3	274.4	277.2
SD	8.7	10.5	14.9	19.0	22.4	24.5	26.1	27.9
N	10	10	10	10	10	10	10	10
%dev	-	-	-	-	-	-	-	-
<b>Male, Gr 1 1.5 mg/m³</b>								
Mean	231.2	225.2	235.5	244.6	254.9	264.9	279.2	286.0
SD	9.9	7.7	10.1	13.4	15.3	17.7	20.7	20.5
N	10	10	10	10	10	10	10	10
%dev	-0.6	0.1	1.3	3.1	2.0	2.2	1.7	3.2
<b>Male, Gr 2 3 mg/m³</b>								
Mean	230.7	226.3	234.9	239.0	250.8	259.5	274.8	282.0
SD	11.5	13.1	15.8	20.3	21.6	20.4	26.7	26.3
N	10	10	10	10	10	10	10	10
%dev	-0.8	0.6	1.0	0.8	0.4	0.1	0.1	1.7
<b>Male, Gr 3 8 mg/m³</b>								
Mean	231.6	226.2	232.3	238.6	247.2	255.7	272.3	277.2
SD	7.5	9.4	11.9	13.9	13.3	13.9	13.5	14.3
N	10	10	10	10	10	10	10	10
%dev	-0.4	0.6	-0.1	0.6	-1.1	-1.4	-0.8	-0.0

Key: 0 = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

Print Date: 14-Nov-2001  
 Print Time: 11:27:52  
 Table : 1A  
 Page : 16

## BODY WEIGHT

	Body Weight g Day 0	Body Weight g Day 47	Body Weight g Day 54	Body Weight g Day 61	Body Weight g Day 68	Body Weight g Day 75	Body Weight g Day 82	Body Weight g Day 89	Body Weight g Day 96
<b>Male, Gr 0 0 mg/m³</b>									
Mean	294.1	290.8	292.4	298.8	309.2	315.7	318.1	325.3	
SD	27.1	30.7	31.7	31.9	33.4	33.7	34.0	36.3	
N	10	10	10	10	10	10	10	10	
%dev									
<b>Male, Gr 1 1.5 mg/m³</b>									
Mean	303.0	305.4	306.7	313.1	319.4	321.2	323.0	329.4	
SD	22.7	24.6	24.8	27.7	29.1	28.5	27.9	26.7	
N	10	10	10	10	10	10	10	10	
%dev	3.0	5.0	4.9	4.8	3.3	1.7	1.5	1.3	
<b>Male, Gr 2 3 mg/m³</b>									
Mean	296.1	300.0	300.8	309.0	316.8	328.4	328.2	335.1	
SD	25.6	27.9	33.2	29.6	29.4	30.9	27.6	29.0	
N	10	10	10	10	10	10	10	10	
%dev	0.7	3.2	2.9	3.4	2.5	4.0	3.2	3.0	
<b>Male, Gr 3 8 mg/m³</b>									
Mean	292.3	292.7	296.7	299.2	308.4	312.9	318.5	323.4	
SD	12.9	15.9	14.9	15.6	17.5	17.4	18.4	19.7	
N	10	10	10	10	10	10	10	10	
%dev	-0.6	-0.6	0.7	1.5	0.1	-0.3	-0.9	-0.6	

Key: 0 = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

BASF - DATATOX-F1 R11

Study: 5110299/99125

BODY WEIGHT

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Body Weight  
g  
Day 103  
D

Male, Gr 0 0 mg/m<sup>3</sup>

Mean 327.4  
SD 37.4  
N 10  
%dev 10

Male, Gr 1 1.5 mg/m<sup>3</sup>

Mean 334.8  
SD 29.7  
N 10  
%dev 2.3

Male, Gr 2 3 mg/m<sup>3</sup>

Mean 335.7  
SD 29.3  
N 10  
%dev 2.5

Male, Gr 3 8 mg/m<sup>3</sup>

Mean 327.3  
SD 20.0  
N 10  
%dev -0.0

Key: D = Dunnett's test. Two-sided, \* = 0.050, \*\* = 0.010  
Experimental Unit = Animal

## BODY WEIGHT

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	Body Weight g Day -5 D	Body Weight g Day 0 D	Body Weight g Day 3 D	Body Weight g Day 10 D	Body Weight g Day 17 D	Body Weight g Day 24 D	Body Weight g Day 31 D	Body Weight g Day 38 D
--	---------------------------------	--------------------------------	--------------------------------	---------------------------------	---------------------------------	---------------------------------	---------------------------------	---------------------------------

## Female, Gr 0 0 mg/m\*3

Mean	162.8	166.7	166.0	172.6	180.9	187.4	193.9	198.9
SD	5.2	6.3	7.5	9.0	11.4	11.3	11.7	11.5
N	10	10	10	10	10	10	10	10
%dev								

## Female, Gr 1 1.5 mg/m\*3

Mean	161.3	166.8	166.4	172.5	179.2	185.9	191.4	196.6
SD	7.8	7.5	7.6	7.4	7.9	8.7	9.9	9.8
N	10	10	10	10	10	10	10	10
%dev	-0.9	0.1	0.3	-0.1	-0.9	-0.8	-1.3	-1.2

## Female, Gr 2 3 mg/m\*3

Mean	161.6	164.6	164.6	170.7	176.8	181.6	187.8	191.6
SD	5.3	5.7	6.4	7.7	7.3	7.8	7.4	7.6
N	10	10	10	10	10	10	10	10
%dev	-0.7	-1.2	-0.8	-1.1	-2.3	-3.1	-3.7	-3.1

## Female, Gr 3 8 mg/m\*3

Mean	160.7	166.8	167.0	172.7	180.5	187.3	193.9	197.2
SD	5.6	5.4	4.8	5.5	6.1	4.5	6.1	4.5
N	10	10	10	10	10	10	10	10
%dev	-1.3	0.1	0.6	0.1	-0.2	-0.1	-0.8	-0.0

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

## BODY WEIGHT

	Body Weight g Day 45 D	Body Weight g Day 52 D	Body Weight g Day 59 D	Body Weight g Day 65 D	Body Weight g Day 73 D	Body Weight g Day 80 D	Body Weight g Day 86 D	Body Weight g Day 94 D
<b>Female, Gr 0 0 mg/m³</b>								
Mean	203.5	204.4	209.3	211.3	216.2	218.2	219.0	220.2
SD	11.8	12.5	14.9	14.6	14.5	14.5	15.4	15.8
N	10	10	10	10	10	10	10	10
%dev								
<b>Female, Gr 1 1.5 mg/m³</b>								
Mean	199.9	202.2	203.1	204.3	206.7	208.9	209.7	215.0
SD	10.4	10.2	10.3	9.2	10.5	11.0	12.2	12.2
N	10	10	10	10	10	10	10	10
%dev	-1.7	-1.1	-3.0	-3.3	-4.4	-4.2	-4.3	-2.4
<b>Female, Gr 2 3 mg/m³</b>								
Mean	194.7	196.6	198.8	201.6	205.1	207.7	209.7	211.8
SD	7.9	9.5	9.7	9.0	9.6	10.3	9.4	9.8
N	10	10	10	10	10	10	10	10
%dev	-4.3	-3.8	-5.0	-4.6	-5.2	-4.8	-4.3	-3.8
<b>Female, Gr 3 8 mg/m³</b>								
Mean	202.3	205.7	207.7	210.1	211.2	214.3	213.9	218.1
SD	8.1	6.9	8.2	8.6	8.0	8.1	7.9	7.9
N	10	10	10	10	10	10	10	10
%dev	-0.6	0.6	-0.8	-0.6	-2.3	-1.8	-2.4	-1.0

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

BASF - DATATOX-F1 R11

Study: 5110299/99125

BODY WEIGHT

Body Weight  
g  
Day 101  
D

Female, Gr 0 0 mg/m<sup>3</sup>

Mean	219.9
SD	14.5
N	10
%dev	

Female, Gr 1 1.5 mg/m<sup>3</sup>

Mean	215.3
SD	12.1
N	10
%dev	-2.1

Female, Gr 2 3 mg/m<sup>3</sup>

Mean	212.7
SD	10.2
N	10
%dev	-3.3

Female, Gr 3 8 mg/m<sup>3</sup>

Mean	218.8
SD	12.0
N	10
%dev	-0.5

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
Experimental Unit = Animal

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## BODY WEIGHT

	Day -5	Day 0	Day 3	Day 6	Day 10	Day 13	Day 17	Day 24	Day 31	Day 38
<b>Female, Gr 01 0 mg/m³</b>										
Mean	162.8	167.8	169.2	174.1	181.4	188.1	193.9	197.8		
SD	4.9	6.0	5.1	6.8	7.5	7.5	8.3	8.9		
N	9	9	9	10	10	9	9	9		
%dev										
<b>Female, Gr 21 3 mg/m³</b>										
Mean	163.2	166.6	166.5	173.3	179.1	186.5	192.8	196.7		
SD	6.6	8.6	8.4	10.2	12.1	12.0	10.9	14.6		
N	10	10	10	10	10	10	10	10		
%dev	0.2	-0.7	-0.7	-1.6	-0.5	-1.2	-0.9	-0.6		
<b>Female, Gr 31 8 mg/m³</b>										
Mean	161.5	165.7	166.8	170.6	179.2	189.4	196.3	199.8		
SD	6.7	8.0	7.9	9.2	10.3	12.9	13.7	13.2		
N	10	10	10	10	10	10	10	10		
%dev	-0.8	-1.3	-1.4	-2.0	-1.2	0.7	1.2	1.0		

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

Study: 5110299/99125

## BODY WEIGHT

	Body Weight g Day 45 0	Body Weight g Day 52 0	Body Weight g Day 59 0	Body Weight g Day 65 0	Body Weight g Day 73 0	Body Weight g Day 80 0	Body Weight g Day 86 0	Body Weight g Day 94 0
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## Female, Gr 01 0 mg/m³

Mean	200.8	203.2	207.0	210.9	213.9	217.1	218.0	220.4
SD	9.1	8.5	8.0	8.3	9.9	9.7	8.8	9.7
N	9	9	9	9	9	9	9	9
%dev								

## Female, Gr 21 3 mg/m³

Mean	200.9	203.2	205.1	209.9	211.9	213.7	213.8	217.1
SD	14.6	14.8	15.2	17.0	18.0	17.7	17.4	19.1
N	10	10	10	10	10	10	10	10
%dev	0.0	0.0	-0.9	-0.5	-0.9	-1.5	-1.9	-1.5

## Female, Gr 31 8 mg/m³

Mean	205.0	205.7	207.2	209.4	212.1	214.5	218.8	221.2
SD	13.1	13.2	14.3	13.5	13.8	16.7	15.2	15.8
N	10	10	10	10	10	10	10	10
%dev	2.1	1.2	0.1	-0.7	-0.9	-1.2	0.3	0.3

Key: D = Dunnett's test, [Two-sided, \* = 0.050, \*\* = 0.010]  
 Experimental Unit = Animal

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Study: 5110299/99125

BODY WEIGHT

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Body Weight  
g  
Day 101  
D

Female, Gr 01 0 mg/m<sup>3</sup>

Mean	220.8
SD	8.4
N	9
%dev	

Female, Gr 21 3 mg/m<sup>3</sup>

Mean	220.0
SD	19.5
N	10
%dev	-0.4

Female, Gr 31 8 mg/m<sup>3</sup>

Mean	223.1
SD	15.0
N	10
%dev	1.0

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
Experimental Unit = Animal

BASF - DATATOX-F1 R11

Study: 5110299/99125

## BODY WEIGHT

	Body Weight g	Body Weight Day 108 g	Body Weight Day 115 g	Body Weight Day 122 g	Body Weight Day 129 g	Body Weight Day 136 g	Body Weight Day 143 g	Body Weight Day 150 g	Body Weight Day 157 g
D	D	D	D	D	D	D	D	D	D
Female, Gr 01 0 mg/m³									
Mean	227.8	234.4	236.0	238.6	241.5	243.7	247.6	246.4	
SD	10.1	9.7	11.1	9.5	11.0	13.7	14.0	13.4	
N	9	9	9	9	9	9	9	9	
%dev									
Female, Gr 21 3 mg/m³									
Mean	224.6	228.8	231.4	233.5	235.6	240.0	244.0	238.5	
SD	20.0	19.6	17.6	18.6	18.8	20.7	19.6	16.9	
N	10	10	10	10	10	10	10	10	
%dev	-1.4	-2.4	-2.0	-2.2	-2.4	-1.5	-1.5	-3.2	
Female, Gr 31 8 mg/m³									
Mean	226.5	227.4	232.4	236.2	240.2	234.7	246.9	246.5	
SD	18.3	21.6	20.7	21.5	23.5	37.4	15.8	16.4	
N	10	10	10	10	10	10	9	9	
%dev	-0.6	-3.0	-1.5	-1.0	-0.5	-3.7	-0.3	0.0	

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

## BODY WEIGHT

	Body Weight g	Body Weight g	Body Weight g	Body Weight g
	Day 164	Day 171	Day 178	Day 185
D	0	0	0	0

Female, Gr 01 0 mg/m<sup>3</sup>

	Mean	SD	N	%dev
	251.3	15.1	9	
	15.3	9		

Female, Gr 21 3 mg/m<sup>3</sup>

	Mean	SD	N	%dev
	241.0	17.8	10	-4.1
	20.0	10	10	-2.4

Female, Gr 31 8 mg/m<sup>3</sup>

	Mean	SD	N	%dev
	251.2	16.9	9	-0.0
	16.4	9	0.2	

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

	Body Weight g	Body Weight g	Body Weight g	Body Weight g
	Day 164	Day 171	Day 178	Day 185
D	0	0	0	0

Female, Gr 01 0 mg/m<sup>3</sup>

	Mean	SD	N	%dev
	251.6	15.3	9	
	12.2	9		

	Mean	SD	N	%dev
	252.1	15.0	9	
	12.2	9		

	Mean	SD	N	%dev
	255.1	15.0	9	
	12.2	9		

	Mean	SD	N	%dev
	256.6	14.3	9	
	14.3	9		

## Study: 5110299/99125

## BODY WEIGHT CHANGE

	BW change g Day -3	BW change g Day 0	BW change g Day 5	BW change g Day 12	BW change g Day 19	BW change g Day 26	BW change g Day 33	BW change g Day 40
	D	D	D	D	D	D	D	D
<b>Male, Gr 0 0 mg/m³</b>								
Mean	7.8	0.0	7.6	12.2	25.0	34.4	49.5	52.3
SD	4.9	0.0	5.0	9.5	13.0	15.3	17.1	18.8
N	10	10	10	10	10	10	10	10
%dev								
<b>Male, Gr 1 1.5 mg/m³</b>								
Mean	6.0	0.0	10.3	19.4	29.8	39.8	54.1	60.9
SD	3.8	0.0	4.8	7.9	8.7	11.7	14.1	13.9
N	10	10	10	10	10	10	10	10
%dev	-22.8	NC	36.2	58.7	19.2	15.6	9.1	16.3
<b>Male, Gr 2 3 mg/m³</b>								
Mean	4.4	0.0	8.5	12.6	24.5	33.2	48.5	55.7
SD	5.5	0.0	5.4	8.5	10.9	8.9	15.2	15.1
N	10	10	10	10	10	10	10	10
%dev	-43.5	NC	12.7	3.0	-1.8	-3.5	-2.1	6.4
<b>Male, Gr 3 8 mg/m³</b>								
Mean	5.4	0.0	6.1	12.4	20.9	29.4	46.0	50.9
SD	4.9	0.0	3.5	6.1	7.1	8.6	8.6	10.0
N	10	10	10	10	10	10	10	10
%dev	-30.5	NC	-19.5	1.2	-16.2	-14.5	-7.1	-2.7

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

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## Study: 5110299/99125

				BODY WEIGHT CHANGE					
				BW change g	BW change g	BW change g	BW change g	BW change g	BW change g
				Day 47	Day 54	Day 61	Day 68	Day 75	Day 82
	D	D	D						D
Male, Gr 0 0 mg/m <sup>3</sup>									
Mean	69.2	65.9	67.5	73.9	84.3	90.8	93.2	100.4	
SD	18.0	21.8	22.9	23.1	25.0	25.1	25.7	28.0	
N	10	10	10	10	10	10	10	10	
%dev									
Male, Gr 1 1.5 mg/m <sup>3</sup>									
Mean	77.8	80.2	81.5	87.9	94.2	96.0	97.9	104.3	
SD	16.1	17.9	18.7	20.8	22.4	21.9	21.2	19.8	
N	10	10	10	10	10	10	10	10	
%dev									
Male, Gr 2 3 mg/m <sup>3</sup>									
Mean	69.8	73.6	74.4	82.7	90.4	102.1	101.8	108.8	
SD	14.5	17.0	23.7	20.5	19.9	21.6	17.8	19.0	
N	10	10	10	10	10	10	10	10	
%dev									
Male, Gr 3 8 mg/m <sup>3</sup>									
Mean	66.0	66.5	70.4	73.0	82.2	86.6	92.3	97.1	
SD	8.9	11.1	11.4	11.9	13.1	13.1	13.5	14.8	
N	10	10	10	10	10	10	10	10	
%dev									

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

## BODY WEIGHT CHANGE

## BW change

g

Day 103

D

Male, Gr 0 0 mg/m<sup>3</sup>

Mean	102.5
SD	29.4
N	10
%dev	

Male, Gr 1 1.5 mg/m<sup>3</sup>

Mean	109.7
SD	22.9
N	10
%dev	7.0

Male, Gr 2 3 mg/m<sup>3</sup>

Mean	109.3
SD	18.5
N	10
%dev	6.7

Male, Gr 3 8 mg/m<sup>3</sup>

Mean	101.1
SD	14.8
N	10
%dev	-1.4

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
Experimental Unit = Animal

## Study: 5110299/99125

## BODY WEIGHT CHANGE

	BW change g Day -5	BW change g Day 0	BW change g Day 3	BW change g Day 10	BW change g Day 17	BW change g Day 24	BW change g Day 31	BW change g Day 38
	D	D	D	D	D	D	D	D
<b>Female, Gr 0 0 mg/m³</b>								
Mean	-3.9	0.0	-0.7	5.9	14.2	20.8	27.2	32.2
SD	4.1	0.0	3.7	3.4	5.9	5.7	6.2	6.5
N	10	10	10	10	10	10	10	10
%dev								
<b>Female, Gr 1 1.5 mg/m³</b>								
Mean	-5.5	0.0	-0.3	5.7	12.5	19.1	24.6	29.8
SD	4.8	0.0	2.8	3.8	3.2	3.8	4.2	4.7
N	10	10	10	10	10	10	10	10
%dev								
<b>Female, Gr 2 3 mg/m³</b>								
Mean	-3.0	0.0	0.0	6.1	12.2	17.0	23.3	27.0
SD	3.2	0.0	3.1	3.8	3.7	4.1	4.6	4.5
N	10	10	10	10	10	10	10	10
%dev								
<b>Female, Gr 3 8 mg/m³</b>								
Mean	-6.1	0.0	0.2	6.0	13.7	20.5	27.1	30.4
SD	3.1	0.0	2.2	3.7	4.9	6.9	4.7	5.8
N	10	10	10	10	10	10	10	10
%dev								

Female, Gr 0 0 mg/m³	D	D	D	D	D	D	D	D
Mean	-3.9	0.0	-0.7	5.9	14.2	20.8	27.2	32.2
SD	4.1	0.0	3.7	3.4	5.9	5.7	6.2	6.5
N	10	10	10	10	10	10	10	10
%dev								
Female, Gr 1 1.5 mg/m³	D	D	D	D	D	D	D	D
Mean	-5.5	0.0	-0.3	5.7	12.5	19.1	24.6	29.8
SD	4.8	0.0	2.8	3.8	3.2	3.8	4.2	4.7
N	10	10	10	10	10	10	10	10
%dev								
Female, Gr 2 3 mg/m³	D	D	D	D	D	D	D	D
Mean	-3.0	0.0	0.0	6.1	12.2	17.0	23.3	27.0
SD	3.2	0.0	3.1	3.8	3.7	4.1	4.6	4.5
N	10	10	10	10	10	10	10	10
%dev								
Female, Gr 3 8 mg/m³	D	D	D	D	D	D	D	D
Mean	-6.1	0.0	0.2	6.0	13.7	20.5	27.1	30.4
SD	3.1	0.0	2.2	3.7	4.9	6.9	4.7	5.8
N	10	10	10	10	10	10	10	10
%dev								

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

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## Study: 5110299/99125

## BODY WEIGHT CHANGE

	BW change g Day 45	BW change g Day 52	BW change g Day 59	BW change g Day 65	BW change g Day 73	BW change g Day 80	BW change g Day 86	BW change g Day 94
	D	D	D	D	D	D	D	D
Female, Gr 0 0 mg/m <sup>3</sup>								
Mean	36.8	37.7	42.6	44.6	49.6	51.5	52.4	53.6
SD	6.8	7.3	9.9	9.4	9.5	10.0	10.8	11.1
N	10	10	10	10	10	10	10	10
%dev								

Female, Gr 1 1.5 mg/m<sup>3</sup>

Mean	33.2	35.4	36.3	37.6	40.0*	42.2*	42.9*	48.3
SD	4.3	4.1	3.8	3.5	4.1	4.9	5.9	5.5
N	10	10	10	10	10	10	10	10
%dev	-9.9	-6.1	-14.8	-15.8	-19.4	-18.1	-18.1	-9.8
Female, Gr 2 3 mg/m <sup>3</sup>								
Mean	30.1*	32.0	34.2*	37.0	40.5*	43.1	45.1	47.2
SD	4.9	7.3	7.1	5.8	6.8	7.8	6.6	7.5
N	10	10	10	10	10	10	10	10
%dev	-18.3	-15.1	-19.8	-17.0	-18.3	-16.3	-13.9	-11.9
Female, Gr 3 8 mg/m <sup>3</sup>								
Mean	35.5	38.9	40.9	43.3	44.5	47.5	47.1	51.3
SD	7.3	6.3	6.9	7.5	8.3	7.7	6.8	6.8
N	10	10	10	10	10	10	10	10
%dev	-3.4	3.1	-4.0	-2.9	-10.3	-7.7	-10.1	-4.2

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

BW change  
g  
Day 101

D

Female, Gr 0 0 mg/m<sup>3</sup>

Mean	53.3
SD	10.0
N	10
%dev	

Female, Gr 1 1.5 mg/m<sup>3</sup>

Mean	48.6
SD	5.1
N	10
%dev	-8.8

Female, Gr 2 3 mg/m<sup>3</sup>

Mean	48.1
SD	8.0
N	10
%dev	-9.6

Female, Gr 3 8 mg/m<sup>3</sup>

Mean	52.0
SD	12.8
N	10
%dev	-2.3

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
Experimental Unit = Animal

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## BODY WEIGHT CHANGE

	BW change g Day -5	BW change g Day 0	BW change g Day 3	BW change g Day 10	BW change g Day 17	BW change g Day 24	BW change g Day 31	BW change g Day 38
D	D	D	D	D	D	D	D	D

## Female, Gr 01 0 mg/m³\*3

Mean	-5.0	0.0	1.4	6.3	12.6	19.5	25.5	29.4
SD	2.4	0.0	2.0	1.7	3.4	3.4	4.7	6.0
N	9	9	9	9	9	8	8	8
%dev								

## Female, Gr 21 3 mg/m³\*3

Mean	-3.4	0.0	-0.1	6.7	12.6	19.9	26.2	30.1
SD	2.5	0.0	2.9	3.0	3.8	4.4	3.6	7.1
N	10	10	10	10	10	10	10	10
%dev	-32.1	NC	-106.6	6.5	-0.7	2.2	2.7	2.2

## Female, Gr 31 8 mg/m³\*3

Mean	-4.2	0.0	1.1	4.9	13.5	23.7	30.6	34.1
SD	2.8	0.0	1.4	3.3	4.7	5.9	6.8	6.7
N	10	10	10	10	10	10	10	10
%dev	-16.0	NC	-21.0	-21.9	-21.9	21.7	20.1	15.9

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

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BODY WEIGHT CHANGE

	BW change g Day 45	BW change g Day 52	BW change g Day 59	BW change g Day 65	BW change g Day 73	BW change g Day 80	BW change g Day 86	BW change g Day 94
D	D	D	D	D	D	D	D	D
Female, Gr 01 0 mg/m³								
Mean	31.7	34.4	38.3	41.9	44.6	47.9	49.2	51.8
SD	5.4	6.3	6.1	6.1	7.5	8.2	6.8	8.2
N	8	8	8	8	8	8	8	8
%dev								
Female, Gr 21 3 mg/m³								
Mean	34.3	36.7	38.5	43.3	45.3	47.1	47.2	50.6
SD	8.1	7.8	8.7	10.3	11.1	11.0	10.4	12.4
N	10	10	10	10	10	10	10	10
%dev								-2.5
Female, Gr 31 8 mg/m³								
Mean	39.3	40.0	41.5	43.7	46.3	48.8	53.0	55.5
SD	7.7	7.0	8.2	7.5	7.8	10.8	9.9	10.5
N	10	10	10	10	10	10	10	10
%dev								7.0

Key: D = Dunnett's test, Two-sided, \* = 0.050, \*\* = 0.010  
Experimental Unit = Animal

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BW change

g

Day 101

D

Female, Gr 01 0 mg/m<sup>3</sup>

Mean	51.8
SD	7.1
N	8
%dev	

Female, Gr 21 3 mg/m<sup>3</sup>

Mean	53.4
SD	13.0
N	10
%dev	3.0

Female, Gr 31 8 mg/m<sup>3</sup>

Mean	57.4
SD	9.7
N	10
%dev	10.7

Key: D = Dunnett's test. Two-sided. \* = 0.050, \*\* = 0.010  
Experimental Unit = Animal

## Study: 5110299/99125

## BODY WEIGHT CHANGE

	BW change g					
	Day 108	Day 115	Day 122	Day 129	Day 136	Day 143
D	0	0	0	0	0	0
Female, Gr 01 0 mg/m³						
Mean	58.6	66.2	67.8	70.4	73.2	75.5
SD	8.9	9.3	11.1	9.4	12.0	13.4
N	8	8	8	8	8	8
%dev						

## Female, Gr 21 3 mg/m³

Mean	58.0	62.2	64.8	66.9	69.0	73.4	77.4	71.9
SD	13.8	13.5	11.6	13.2	13.4	14.5	13.7	11.2
N	10	10	10	10	10	10	10	10
%dev	-1.0	-6.1	-4.4	-5.0	-5.7	-2.7	-3.4	-8.6
Female, Gr 31 8 mg/m³								
Mean	60.8	61.7	66.7	70.5	74.5	69.0	79.9	79.5
SD	12.3	15.4	15.3	15.7	17.4	31.7	11.1	10.8
N	10	10	10	10	10	10	9	9
%dev	3.8	-6.8	-1.6	0.2	1.7	-8.6	-0.3	1.1

Key: D = Dunnett's test. Two-sided. \* = 0.050, \*\* = 0.010  
 Experimental Unit = Animal

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BODY WEIGHT CHANGE

	BW change g Day 164	BW change g Day 171	BW change g Day 178	BW change g Day 185	BW change g Day 191
D	D	D	D	D	D

Female, Gr 01 0 mg/m<sup>3</sup>

Mean	84.2	84.8	85.5	88.1	90.2
SD	15.4	14.5	10.3	13.5	13.3
N	8	8	8	8	8
%dev					

Female, Gr 21 3 mg/m<sup>3</sup>

Mean	74.4	79.0	79.6	77.6	80.0
SD	12.8	14.3	16.1	13.7	14.9
N	10	10	10	10	10
%dev	-11.7	-6.8	-6.8	-11.9	-11.4

Female, Gr 31 8 mg/m<sup>3</sup>

Mean	84.2	84.0	83.6	85.1	86.2
SD	11.2	11.2	10.5	9.7	11.4
N	9	9	9	9	9
%dev	0.0	-0.9	-2.2	-3.4	-4.4

Key: D = Dunnett's test, Two-sided. \* = 0.050, \*\* = 0.010  
Experimental Unit = Animal

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ABSOLUTE WEIGHTS - MEAN VALUES (MALE) F1

Sacrifice group		F1			
Sex		M			
Dose group		0	1	2	3
Terminal body weight	g	M	305.06	311.87	312.64
		SD	34.825	28.084	29.183
		n	10	10	10
Liver	g	M	7.74	7.552	7.717
		SD	1.39	0.688	0.726
		n	10	10	10
Lungs	g	M	0.962	0.929	0.934
		SD	0.098	0.107	0.086
		n	10	10	10
Kidneys	g	M	1.926	1.95	1.937
		SD	0.306	0.183	0.171
		n	10	10	10
Testes	g	M	3.158	3.163	3.107
		SD	0.497	0.394	0.367
		n	10	10	10
Heart	g	M	0.919	0.943	0.949
		SD	0.096	0.054	0.104
		n	10	10	10
Spleen	g	M	0.622	0.616	0.628
		SD	0.071	0.084	0.095
		n	10	10	10
Brain	g	M	1.906	1.898	1.909
		SD	0.086	0.07	0.071
		n	10	10	10
Adrenal glands	mg	M	62.5	60.1	62.3
		SD	6.223	7.738	9.031
		n	10	10	10

\* P <= 0.05 \*\* P <= 0.01 :Kruskal-Wallis-H- + Wilcoxon-Test  
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ABSOLUTE WEIGHTS - MEAN VALUES (FEMALE) F1

Sacrifice group		F1			
Sex		F			
Dose group		0	1	2	3
Terminal body weight	g	M	204.83	195.94	195.68
		SD	13.696	10.75	9.601
		n	10	10	10
Liver	g	M	5.375	5.14	5.001*
		SD	0.617	0.714	0.346
		n	10	10	10
Lungs	g	M	0.776	0.778	0.79
		SD	0.072	0.066	0.071
		n	10	10	10
Kidneys	g	M	1.381	1.347	1.333
		SD	0.058	0.096	0.041
		n	10	10	10
Heart	g	M	0.68	0.683	0.668
		SD	0.041	0.042	0.053
		n	10	10	10
Spleen	g	M	0.469	0.475	0.482
		SD	0.06	0.035	0.07
		n	10	10	10
Brain	g	M	1.808	1.811	1.819
		SD	0.07	0.046	0.041
		n	10	10	10
Adrenal glands	mg	M	73.1	73.6	65.0
		SD	11.752	10.458	7.944
		n	10	10	10

\* P <= 0.05 \*\* P <= 0.01 :Kruskal-Wallis-H- + Wilcoxon-Test  
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RELATIVE WEIGHTS - MEAN VALUES (MALE) F1

Sacrifice group		F1			
		M			
<u>Dose group</u>		0	1	2	3
Terminal body weight	z	M 100.0 n 10	100.0 10	100.0 10	100.0 10
Liver	z	M 2.532 SD 0.328 n 10	2.423 0.092 10	2.47 0.111 10	2.449 0.198 10
Lungs	z	M 0.316 SD 0.019 n 10	0.298 0.023 10	0.3 0.023 10	0.328 0.012 10
Kidneys	z	M 0.629 SD 0.048 n 10	0.626 0.039 10	0.621 0.041 10	0.631 0.046 10
Testes	z	M 1.034 SD 0.102 n 10	1.013 0.079 10	0.998 0.126 10	1.021 0.096 10
Heart	z	M 0.302 SD 0.013 n 10	0.303 0.016 10	0.304 0.022 10	0.29 0.022 10
Spleen	z	M 0.205 SD 0.024 n 10	0.197 0.018 10	0.201 0.028 10	0.203 0.023 10
Brain	z	M 0.63 SD 0.05 n 10	0.612 0.041 10	0.614 0.046 10	0.619 0.025 10
Adrenal glands	z	M 0.021 SD 0.002 n 10	0.019 0.003 10	0.02 0.003 10	0.02 0.002 10

\* P <= 0.05 \*\* P <= 0.01 :Kruskal-Wallis-H- + Wilcoxon-Test  
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RELATIVE WEIGHTS - MEAN VALUES (FEMALE) F1

Sacrifice group		F1			
Sex		F			
Dose group		0	1	2	3
Terminal body weight	%	M	100.0	100.0	100.0
		n	10	10	10
Liver	%	M	2.624	2.618	2.556
		SD	0.262	0.275	0.131
		n	10	10	10
Lungs	%	M	0.38	0.399	0.404
		SD	0.037	0.051	0.03
		n	10	10	10
Kidneys	%	M	0.676	0.688	0.682
		SD	0.044	0.047	0.031
		n	10	10	10
Heart	%	M	0.332	0.349	0.342
		SD	0.01	0.015	0.023
		n	10	10	10
Spleen	%	M	0.23	0.243	0.246
		SD	0.032	0.019	0.034
		n	10	10	10
Brain	%	M	0.886	0.927	0.931
		SD	0.068	0.057	0.046
		n	10	10	10
Adrenal glands	%	M	0.036	0.038	0.033
		SD	0.006	0.005	0.004
		n	10	10	10

\* P <= 0.05 \*\* P <= 0.01 :Kruskal-Wallis-H- + Wilcoxon-Test  
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## ABSOLUTE WEIGHTS - MEAN VALUES (FEMALE) R1

Sacrifice group		R1		
Sex		F		
Dose group		0	2	3
Terminal body weight	g	M	240.833	232.27
		SD	12.291	18.564
		n	9	10
Liver	g	M	5.769	5.771
		SD	0.446	0.672
		n	9	10
Lungs	g	M	0.859	0.842
		SD	0.056	0.082
		n	9	10
Kidneys	g	M	1.414	1.449
		SD	0.101	0.132
		n	9	10
Heart	g	M	0.744	0.772
		SD	0.076	0.094
		n	9	10
Spleen	g	M	0.588	0.549
		SD	0.077	0.105
		n	9	10
Brain	g	M	1.89	1.896
		SD	0.072	0.067
		n	9	10
Adrenal glands	mg	M	75.0	70.9
		SD	10.735	6.79
		n	9	10

\* P <= 0.05 \*\* P <= 0.01 :Kruskal-Wallis-H- + Wilcoxon-Test  
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RELATIVE WEIGHTS - MEAN VALUES (FEMALE) R1

Sacrifice group		R1		
Sex		F		
Dose group		0	2	3
Terminal body weight	%	M	100.0	100.0
		n	9	10
Liver	%	M	2.396	2.479
		SD	0.143	0.124
		n	9	10
Lungs	%	M	0.357	0.364
		SD	0.021	0.035
		n	9	10
Kidneys	%	M	0.587	0.625
		SD	0.026	0.048
		n	9	10
Heart	%	M	0.309	0.333
		SD	0.025	0.031
		n	9	10
Spleen	%	M	0.244	0.236
		SD	0.031	0.039
		n	9	10
Brain	%	M	0.786	0.82
		SD	0.046	0.06
		n	9	10
Adrenal glands	%	M	0.031	0.031
		SD	0.004	0.002
		n	9	10

\* P <= 0.05 \*\* P <= 0.01 :Kruskal-Wallis-H- + Wilcoxon-Test  
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INCIDENCE OF GROSS LESIONS F1

Sacrifice group	F1									
Sex	M	0	1	2	3	F	0	1	2	3
<u>Dose group</u>	0	10	10	10	10	0	10	10	10	10
<u>Animals in selected Group</u>	10	10	10	10	10	9	9	9	9	7
NAD	10	7	6	8	9	9	9	9	9	7
Liver	.	.	.	.	.	.	.	.	.	.
- Focal constriction	.	.	.	.	.	.	.	.	1	.
- Focus	.	1	1	.	.	.	.	.	.	.
Kidneys	.	.	.	.	.	.	.	.	.	.
- Retraction	.	.	1	.	.	.	.	.	.	.
Testes	.	.	.	.	.	.	.	.	.	.
- Focus	.	1	1	.	.	.	.	.	.	.
- Organ size reduced	.	1	.	1	.	.	.	.	.	.
Epididymides	.	.	.	.	.	.	.	.	.	.
- Abscess	.	1	.	.	.	.	.	.	.	.
- Enlarged	.	.	.	.	1	.	.	.	.	.
Ovaries	.	.	.	.	.	.	.	1	.	.
- Cyst	.	.	.	.	.	.	.	1	.	.
Uterus	.	.	.	.	.	.	.	.	.	.
- Dilation	.	.	.	.	.	.	.	.	.	1
Pituitary gland	.	.	.	.	.	.	.	.	.	.
- Cyst	.	.	.	.	.	.	.	.	.	1
Skin	.	.	.	.	.	.	.	.	.	.
- Decubitus	.	.	.	.	.	.	1	.	.	.
- Sparse hair	.	.	1	.	1	.	1	.	.	1

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INCIDENCE OF GROSS LESIONS R1

Sacrifice group	R1		
Sex	F		
Dose group	0	2	3
Animals in selected Group	10	10	10
NAD	9	7	9
Liver	.	.	.
- Cyst	.	1	.
- Focus	.	1	.
Lungs	.	.	.
- Atelectasis	.	.	1
- Discoloration	1	.	.
Kidneys	.	.	.
- Granular surface	.	.	1
Liver lymph node	.	.	.
- Discoloration	.	1	.
Skin	.	.	.
- Sparse hair	.	1	.

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## INCIDENCE OF MICROSCOPIC FINDINGS F1

Sacrifice group	F1				F				
Sex	M	0	1	2	3	0	1	2	3
Dose group	0	10	10	10	10	10	10	10	10
Animals in selected Group	10	10	10	10	10	10	10	10	10
Liver	10	1	1	10	10	.	1	10	
- Granuloma(s), Kupff.	10	.	.	9	10	.	.	.	10
- Fatty change	4	.	.	1	6	.	.	.	7
- Pigment storage	.	.	.	.	.	.	.	.	1
- Focal necrosis	.	1	.	.	.	.	.	.	.
- Focal fibrosis	.	.	1	.	.	.	.	1	.
Nasal cavity, I	10	10	10	10	10	10	10	10	10
Nasal cavity, II	10	10	10	10	10	10	10	10	10
Nasal cavity, III	10	10	10	10	10	10	10	10	10
Nasal cavity, IV	10	10	10	10	10	10	10	10	10
Larynx, level I	10	10	10	10	10	10	10	10	10
- Metaplasia, squamous	.	.	3	9	.	.	.	.	9
- Inflammatory cells	2	1	.	3	1	.	.	.	3
Larynx, level II	10	10	10	10	10	10	10	10	10
- Metaplasia, squamous	.	.	.	2	.	.	.	.	.
Larynx, level III	10	10	10	10	10	10	10	10	10
Trachea	10	10	10	10	10	10	10	10	10
Lungs	10	.	.	10	10	.	.	.	10
- Foam cells	1	.	.	2	1	.	.	.	.
- Microgranuloma(s)	.	.	.	2	.	.	.	.	1
- Mineralisat.(artery)	8	.	.	7	5	.	.	.	4
Kidneys	.	.	1	.	.	.	.	.	.
- Nephritis, interst.	.	.	1	.	.	.	.	.	.
Testes	.	2	1	1	.	.	.	.	.
- Tubular atrophy,m(f)	.	1	1	1	.	.	.	.	.
- Calcification	.	.	1	.	.	.	.	.	.
- Congestion	.	1	.	.	.	.	.	.	.
Epididymides	.	1	.	1	.	.	.	.	.
- Sperma granuloma	.	1	.	1	.	.	.	.	.
Ovaries	.	.	.	.	.	1	.	.	.
- Cyst(s)	.	.	.	.	.	1	.	.	.
Uterus	.	.	.	.	.	.	.	.	1
- Dilatation	.	.	.	.	.	.	.	.	1
Mediastinal lymph n.	10	.	.	10	10	.	.	.	10
Pituitary gland	.	.	.	.	.	.	.	.	1
Skin	.	.	1	.	1	1	.	.	1
- Dermatitis, chronic	.	.	.	.	.	1	.	.	.

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INCIDENCE OF MICROSCOPIC FINDINGS R1

Sacrifice group	R1			
Sex	F			
Dose group	0	1	2	3
<u>Animals in selected Group</u>	<u>10</u>	.	<u>10</u>	<u>10</u>
Liver	.	.	2	.
- Pigment storage	.	.	1	.
- Vascular dilation	.	.	1	.
- Hemorrhage, focal	.	.	1	.
Nasal cavity, I	10	.	.	10
- Congestion	1	.	.	.
Nasal cavity, II	10	.	.	10
- Congestion	1	.	.	.
Nasal cavity, III	10	.	.	10
- Congestion	1	.	.	.
Nasal cavity, IV	10	.	.	10
- Congestion	1	.	.	.
Larynx, level I	10	.	.	10
Larynx, level II	10	.	.	10
Larynx, level III	10	.	.	10
Lungs	1	.	.	1
- Congestion	1	.	.	1
Kidneys	.	.	.	1
- Glomerulonephropathy	.	.	.	1
Liver lymph node	.	.	1	.
- Hemosiderosis	.	.	1	.
Skin	.	.	1	.

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INCIDENCE AND GRADINGS OF MICROSCOPIC FINDINGS IN THE LARYNX

Sacrifice group	F1					F			
Sex	M								
Dose group	0	1	2	3		0	1	2	3
<u>Animals in selected Group</u>	10	10	10	10		10	10	10	10
Larynx, level I	10	10	10	10		10	10	10	10
- Metaplasia, squamous	.	.	3	9	.	.	.	.	9
	.	P.	.	3	9	.	.	.	9
- Inflammatory cells	2	1	.	3	1	.	.	.	3
	.	1.	1	.	.	1	.	.	1
	.	2.	1	.	2	.	.	.	2
	.	3.	.	.	1	.	.	.	.
Larynx, level II	10	10	10	10		10	10	10	10
- Metaplasia, squamous	.	.	.	2	.	.	.	.	.
	.	P.	.	.	2	.	.	.	.
Larynx, level III	10	10	10	10		10	10	10	10

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PATHOLOGY REPORT

Diethanolamine: Subchronic Inhalation  
Study in Wistar Rats

IB- 12  
51I0299/99125  
Feb/27/2002 WEKA  
acopat system

INCIDENCE AND GRADINGS OF MICROSCOPIC FINDINGS IN THE LARYNX

Sacrifice group	R1				F				
Sex	M	0	1	2	3	0	1	2	3
Dose group	0	.	.	.	.	10	.	10	10
Animals in selected Group	.	.	.	.	.	10	.	.	10
Larynx, level I	.	.	.	.	.	10	.	.	10
Larynx, level II	.	.	.	.	.	10	.	.	10
Larynx, level III	.	.	.	.	.	10	.	.	10

Table IC - 001 Study means of Exposure parameters

	Supply air 1 Conditioned [m³/h]	SD	Supply air 2 Compressed [m³/h]	SD	Supply air 3 Conditioned [m³/h]	SD	Exhaust air 1 [m³/h]	SD	Exhaust air 2 [m³/h]	SD	Chamber humidity [%RH]	SD	Chamber temperature [°C]	SD	Generator temperature [°C]	SD	Pump rate [ml/h]	SD	Concentration [mg/m³]	SD	Photometer measurements [unit]	SD	
<b>Test Group 0</b>																							
Study Mean	4,49	0,1	1,48	0,2	-	-	5,49	0,1	41,3	1,4	23,0	0,2	-	-	-	-	0,0	0,0	-	-	-	-	
<b>Test Group 1</b>																							
Study Mean	4,50	0,0	1,42	0,0	5,51	0,2	5,51	0,2	5,40	0,1	47,1	1,2	22,5	0,2	49,6	0,4	1,7	0,1	1,57	0,33	2,9	0,6	
<b>Test Group 2</b>																							
Study Mean	4,50	0,0	1,45	0,0	5,43	0,2	5,43	0,2	5,38	0,1	44,9	1,4	23,3	0,2	50,7	0,4	1,7	0,1	3,43	0,80	3,7	1,1	
<b>Test Group 3</b>																							
Study Mean	4,50	0,0	1,49	0,0	4,59	0,1	4,69	0,1	5,34	0,1	45,4	1,9	23,3	0,2	49,9	0,1	1,7	0,1	8,18	1,45	30,0	5,3	

Table IC – 002 Summary of particle size measurements in test group 1 (1.5 mg/m³)

Date of measurement	Number of measurement	MMAD [µm]	GSD	Mass <3 µm [%]	Total Mass [mg]	Mass Impinger [mg]	Impg. [%]	Conc. Impg. [mg/m³]	Conc. Imp. [mg/m³]	Conc. Anal. [mg/m³]
21.03.2001	1	0,8	2,6	92,2	2,635	0,211	8,0	0,29	3,66	1,65
27.03.2001	2*	0,4	-	99,9	0,389	0,000	0,0	0,00	0,54	1,44
02.04.2001	3*	0,4	-	98,5	1,497	0,111	7,4	0,15	2,08	1,53
05.04.2001	4	0,5	5,1	87,4	2,411	0,000	0,0	0,00	3,35	1,54
30.05.2001	5	0,9	2,3	93,3	1,801	0,000	0,0	0,00	2,50	1,83
30.05.2001	6*	0,4	-	99,0	1,664	0,000	0,0	0,00	2,31	1,35
21.06.2001	7	0,4	3,1	96,7	1,683	0,000	0,0	0,00	2,34	1,59
26.06.2001	8	0,6	2,6	95,1	1,644	0,000	0,0	0,00	2,28	1,37
Means		0,6	3,3	95,1	1,73	0,05	2,57	0,07	2,41	1,56
SD		0,2	1,5	4,9	0,79	0,09	3,99	0,12	1,10	0,17

\* From the distribution no MMAD could be reasonably calculated (MMAD <0,4 µm), but 0,4 µm was used for calculation the study mean

Table IC – 003 Summary of particle size measurements in test group 2 (3 mg/m³)

Date of measurement	Number of measurement	MMAD [µm]	GSD	Mass <3 µm [%]	Total Mass [mg]	Mass Impinger [mg]	Impg. [%]	Conc. Impg. [mg/m³]	Conc. Imp. [mg/m³]	Conc. Anal. [mg/m³]
20.03.2001	1	0,9	2,3	93,0	1,375	0,000	0,0	0,00	3,82	2,97
26.03.2001	2	0,6	2,7	95,3	1,321	0,000	0,0	0,00	3,67	4,08
29.03.2001	3	0,4	3,0	96,4	1,895	0,000	0,0	0,00	5,26	3,87
04.04.2001	4	0,5	2,9	96,2	1,782	0,000	0,0	0,00	4,95	3,90
29.05.2001	5	0,5	2,9	96,0	1,287	0,000	0,0	0,00	3,58	3,57
12.06.2001	6*	0,4	-	99,9	1,008	0,000	0,0	0,00	2,80	2,08
Means		0,6	2,8	96,1	1,44	0,00	0,00	0,00	4,01	3,41
SD		0,2	0,3	2,2	0,33	0,00	0,00	0,00	0,92	0,76

\* From the distribution no MMAD could be reasonably calculated (MMAD <0,4 µm), but 0,4 µm was used for calculation the study mean

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Table IC – 004 Summary of particle size measurements in test group 3 (8 mg/m<sup>3</sup>)

Date of measurement	Number of measurement	MMAD [µm]	GSD	Mass <3 µm [%]	Total Mass [mg]	Mass Impinger [mg]	Impg. [%]	Conc. Impg. [mg/m <sup>3</sup> ]	Conc. Imp. [mg/m <sup>3</sup> ]	Conc. Anal. [mg/m <sup>3</sup> ]
19.03.2001	1	0,9	2,3	92,9	1,689	0,000	0,0	0,00	9,38	8,36
22.03.2001	2	0,7	2,5	93,9	1,248	0,000	0,0	0,00	6,93	9,96
28.03.2001	3	0,9	2,3	92,9	1,039	0,000	0,0	0,00	5,77	7,46
03.04.2001	4	0,5	2,8	95,8	1,673	0,000	0,0	0,00	9,29	8,36
28.05.2001	5	0,7	2,5	94,9	2,438	0,000	0,0	0,00	13,54	6,93
11.06.2001	6	0,7	2,5	94,8	2,088	0,000	0,0	0,00	11,60	8,62
Means		0,7	2,5	94,2	1,70	0,00	0,00	0,00	9,42	8,28
	SD	0,2	0,2	1,2	0,52	0,00	0,00	0,00	2,87	1,04

**STUDY TITLE**

Report

**Diethanolamine - Subchronic inhalation toxicity study in Wistar rats**  
liquid aerosol / vapor exposure  
Study focus on irritation of upper respiratory tract

**PERFORMING LABORATORY**

Experimental Toxicology and Ecology  
BASF Aktiengesellschaft  
67056 Ludwigshafen/Rhein, Germany

**LABORATORY PROJECT IDENTIFICATION**

51I0299/99125

**SPONSOR**

CEFIC Amines Sector Group  
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B- 1160 Brussels

**VOLUME II OF III**  
(TABLES SECTION, INDIVIDUAL VALUES)

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*Observations report - Summary- Recovery groups*

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*Body weight*

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## PATHOLOGY (Individual values)

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**Part C:**

## MEASUREMENTS OF EXPOSURE PARAMETERS

- |  |                   |
|--|-------------------|
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**LIST OF ABBREVIATIONS USED IN TABLES IIA****CLINICAL EXAMINATIONS**

#	= number
g	= gram
mg/m <sup>3</sup>	= milligram per cubicmeter
BE	= before exposure
DE	= during exposure
AE	= after exposure

**LIST OF ABBREVIATIONS USED IN TABLES IIB**

F	= female animals
F1	= final sacrifice groups
g	= weight determination in grams
R1	= recovery group
M	= male animals (under sex); mean value (on weight level)
mg	= weight determination in milligrams
mg/m <sup>3</sup>	= milligram per cubicmeter
n	= number of values measured for the determination of mean value and standard deviation
NAD	= number of animals without gross lesions
SD	= standard deviation
%	= percentage related to the reference weight in relative organ weight calculations

**Codes for the status at necropsy:**

1	= planned sacrifice
2	= killed moribund
3	= intercurrent death

**Codes used at finding level:**

The codes are used for a grading system which takes into consideration either the severity or the number or the size of a microscopic finding.

	Severity	Number	Size
Grade 1	Minimal	Very few	Very small
Grade 2	Slight	Few	Small
Grade 3	Moderate	Moderate number; several	Moderate size
Grade 4	Marked; severe	Many	Large
Grade 5	Massive; extreme	Extensive number	Extensive size

Whenever a grading was not used, the microscopic finding was indicated to be present (P).

#### LIST OF ABBREVIATIONS USED IN TABLES IIC

#### ANALYTICAL DATA AND EXPOSURE PARAMETERS

%	= per cent
L, l	= liter
ml/h	= milliliter per hour
m <sup>3</sup> /h	= cubicmeter per hour
mg/m <sup>3</sup>	= milligram per cubicmeter
mg	= milligram
SD	= standard deviation
°C	= degree Celsius
%RH	= per cent relative humidity
MMAD	= mass median aerodynamic diameter 50%
EACD	= effective aerodynamic cut-off diameter 50%
µm	= micrometer
m	= slope from linear regression
b	= intercept from linear regression
r <sup>2</sup>	= squared correlation coefficient
GSD	= Geometrical standard deviation
*	= No reasonable calculation of MMAD was possible because the major amount of test substance was deposited on the residual filter. Therefore the MMAD must be < 0.4 µm

## OBSERVATIONS REPORT - SUMMARY

Print Date: 13-Nov-2001  
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 Table : 11A  
 Page : 1

Date	Sex	Group	Animal	Observation	Days
1	0M	0	1	General observation, Nothing abnormal detected	-3--1
1	0M	0	2	General observation, Nothing abnormal detected	-3--1
1	0M	0	3	General observation, Nothing abnormal detected	-3--1
1	0M	0	4	General observation, Nothing abnormal detected	-3--1
1	0M	0	5	General observation, Nothing abnormal detected	-3--1
1	0M	0	6	General observation, Nothing abnormal detected	-3--1
1	0M	0	7	General observation, Nothing abnormal detected	-3--1
1	0M	0	8	General observation, Nothing abnormal detected	-3--1
1	0M	0	9	General observation, Nothing abnormal detected	-3--1
1	0M	0	10	General observation, Nothing abnormal detected	-3--1
1	1M	1	11	General observation, Nothing abnormal detected	-3--1
1	1M	1	12	General observation, Nothing abnormal detected	-3--1
1	1M	1	13	General observation, Nothing abnormal detected	-3--1
1	1M	1	14	General observation, Nothing abnormal detected	-3--1
1	1M	1	15	General observation, Nothing abnormal detected	-3--1
1	1M	1	16	General observation, Nothing abnormal detected	-3--1
1	1M	1	17	General observation, Nothing abnormal detected	-3--1
1	1M	1	18	General observation, Nothing abnormal detected	-3--1
1	1M	1	19	General observation, Nothing abnormal detected	-3--1
1	1M	1	20	General observation, Nothing abnormal detected	-3--1
1	2M	2	21	General observation, Nothing abnormal detected	-3--1
1	2M	2	22	General observation, Nothing abnormal detected	-3--1
1	2M	2	23	General observation, Nothing abnormal detected	-3--1
2	2M	2	24	General observation, Nothing abnormal detected	-3--1
2	2M	2	25	General observation, Nothing abnormal detected	-3--1
2	2M	2	26	General observation, Nothing abnormal detected	-3--1

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## OBSERVATIONS REPORT - SUMMARY

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Sex	Group	Animal	Observation	Days
F	0	41	General observation, Nothing abnormal detected	-5--3
F	0	42	General observation, Nothing abnormal detected	-5--3
F	0	43	General observation, Nothing abnormal detected	-5--3
F	0	44	General observation, Nothing abnormal detected	-5--3
F	0	45	General observation, Nothing abnormal detected	-5--3
F	0	46	General observation, Nothing abnormal detected	-5--3
F	0	47	General observation, Nothing abnormal detected	-5--3
F	0	48	General observation, Nothing abnormal detected	-5--3
F	0	49	General observation, Nothing abnormal detected	-5--3
F	0	50	General observation, Nothing abnormal detected	-5--3
F	1	51	General observation, Nothing abnormal detected	-5--3
F	1	52	General observation, Nothing abnormal detected	-5--3
F	1	53	General observation, Nothing abnormal detected	-5--3
F	1	54	General observation, Nothing abnormal detected	-5--3
F	1	55	General observation, Nothing abnormal detected	-5--3
F	1	56	General observation, Nothing abnormal detected	-5--3
F	1	57	General observation, Nothing abnormal detected	-5--3
F	1	58	General observation, Nothing abnormal detected	-5--3
F	1	59	General observation, Nothing abnormal detected	-5--3
F	1	60	General observation, Nothing abnormal detected	-5--3
F	2	61	General observation, Nothing abnormal detected	-5--3
F	2	62	General observation, Nothing abnormal detected	-5--3
F	2	63	General observation, Nothing abnormal detected	-5--3
F	2	64	General observation, Nothing abnormal detected	-5--3
F	2	65	General observation, Nothing abnormal detected	-5--3
F	2	66	General observation, Nothing abnormal detected	-5--3

## OBSERVATIONS REPORT - SUMMARY

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Sex	Group	Animal	Observation	Days
F	2	67	General observation, Nothing abnormal detected	-5--3
F	2	68	General observation, Nothing abnormal detected	-5--3
F	2	69	General observation, Nothing abnormal detected	-5--3
F	2	70	General observation, Nothing abnormal detected	-5--3
F	3	71	General observation, Nothing abnormal detected	-5--3
F	3	72	General observation, Nothing abnormal detected	-5--3
F	3	73	General observation, Nothing abnormal detected	-5--3
F	3	74	General observation, Nothing abnormal detected	-5--3
F	3	75	General observation, Nothing abnormal detected	-5--3
F	3	76	General observation, Nothing abnormal detected	-5--3
F	3	77	General observation, Nothing abnormal detected	-5--3
F	3	78	General observation, Nothing abnormal detected	-5--3
F	3	79	General observation, Nothing abnormal detected	-5--3
F	3	80	General observation, Nothing abnormal detected	-5--3

## Study: 5110299/99125      OBSERVATIONS REPORT - SUMMARY

Sex	Group	Animal	Observation	Days
M	0	1	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	0	2	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	0	3	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	0	4	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	0	5	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	0	6	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	0	7	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	0	8	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	0	9	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	0	10	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	1	11	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	1	12	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	1	13	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	1	14	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	1	15	General observation. Nothing abnormal detected Testis, enlarged, left	0(BE)-73(AE) 74(BE)-103(AE)
M	1	16	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	1	17	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	1	18	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	1	19	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	1	20	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	2	21	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	2	22	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	2	23	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	2	24	General observation. Nothing abnormal detected	0(BE)-103(AE)
M	2	25	General observation. Nothing abnormal detected	0(BE)-103(AE)

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Sex	Group	Animal	Observation	Days
M	2	26	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	2	27	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	2	28	General observation, Nothing abnormal detected	0(BE)-13(AE)
		Alopecia, body		14(BE)-103(AE)
M	2	29	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	2	30	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	3	31	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	3	32	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	3	33	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	3	34	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	3	35	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	3	36	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	3	37	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	3	38	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	3	39	General observation, Nothing abnormal detected	0(BE)-103(AE)
M	3	40	General observation, Nothing abnormal detected	0(BE)-103(AE)

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## OBSERVATIONS REPORT - SUMMARY

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Sex	Group	Animal	Observation	Days
F	0	41	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	0	42	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	0	43	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	0	44	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	0	45	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	0	46	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	0	47	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	0	48	General observation, Nothing abnormal detected	0(BE)-101(AE)
			Skin, lesion	
			Alopecia, body	
F	0	49	General observation, Nothing abnormal detected	11(BE)-44(AE)
F	0	50	General observation, Nothing abnormal detected	35(AE)-101(AE)
F	1	51	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	1	52	General observation, Nothing abnormal detected	0(BE)-101(AE)
			Fur, discoloration, yellow	
F	1	53	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	1	54	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	1	55	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	1	56	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	1	57	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	1	58	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	1	59	General observation, Nothing abnormal detected	0(BE)-81(AE)
			Decubitus, hindlimb, right	
F	1	60	General observation, Nothing abnormal detected	84(BE)-101(AE)
F	2	61	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	2	62	General observation, Nothing abnormal detected	0(BE)-101(AE)

## OBSERVATIONS REPORT - SUMMARY

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Study: 5110299/99125

Sex	Group	Animal	Observation	Days
F	2	63	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	2	64	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	2	65	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	2	66	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	2	67	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	2	68	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	2	69	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	2	70	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	3	71	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	3	72	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	3	73	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	3	74	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	3	75	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	3	76	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	3	77	General observation, Nothing abnormal detected Alopecia, body	0(BE)-44(AE) 45(BE)-101(AE)
F	3	78	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	3	79	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	3	80	General observation, Nothing abnormal detected	0(BE)-101(AE)

Sex	Group	Animal	Observation	Days
M	0	1	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	0	2	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	0	3	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	0	4	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	0	5	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	0	6	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	0	7	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	0	8	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	0	9	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	0	10	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	1	11	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	1	12	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	1	13	General observation, Nothing abnormal detected Sacrificed scheduled	104

## OBSERVATIONS REPORT - SUMMARY

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Sex	Group	Animal	Observation	Days
M	1	14	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	1	15	Testis, enlarged, left Sacrificed scheduled	104
M	1	16	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	1	17	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	1	18	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	1	19	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	1	20	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	2	21	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	2	22	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	2	23	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	2	24	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	2	25	General observation, Nothing abnormal detected Sacrificed scheduled	104
M	2	26	General observation, Nothing abnormal detected Sacrificed scheduled	104

## OBSERVATIONS REPORT - SUMMARY

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Sex	Group	Animal	Observation	Days
M	2	27	General observation, Nothing abnormal detected	104
M	2	28	Sacrificed scheduled Alopecia, body	104
M	2	29	Sacrificed scheduled General observation, Nothing abnormal detected	104
M	2	30	Sacrificed scheduled General observation, Nothing abnormal detected	104
M	3	31	Sacrificed scheduled General observation, Nothing abnormal detected	104
M	3	32	Sacrificed scheduled General observation, Nothing abnormal detected	104
M	3	33	Sacrificed scheduled General observation, Nothing abnormal detected	104
M	3	34	Sacrificed scheduled General observation, Nothing abnormal detected	104
M	3	35	Sacrificed scheduled General observation, Nothing abnormal detected	104
M	3	36	Sacrificed scheduled General observation, Nothing abnormal detected	104
M	3	37	Sacrificed scheduled General observation, Nothing abnormal detected	104
M	3	38	Sacrificed scheduled General observation, Nothing abnormal detected	104
M	3	39	Sacrificed scheduled General observation, Nothing abnormal detected	104

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Study: 5110299/99125

OBSERVATIONS REPORT - SUMMARY

Print Date: 13-Nov-2001  
Print Time: 08:41:17  
Table : 1IA  
Page : 12

Sex	Group	Animal	Observation
M	3	40	General observation. Nothing abnormal detected
			Sacrificed scheduled

Days  
104  
104

## OBSERVATIONS REPORT - SUMMARY

Print Date: 13-Nov-2001  
 Print Time: 08:42:22  
 Table : TIA  
 Page : 13

Study: 5110299/99125

Sex	Group	Animal	Observation	Days
F	0	41	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	0	42	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	0	43	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	0	44	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	0	45	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	0	46	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	0	47	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	0	48	Alopecia, body Sacrificed scheduled	102
F	0	49	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	0	50	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	1	51	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	1	52	Fur, discoloration, yellow Sacrificed scheduled	102
F	1	53	General observation, Nothing abnormal detected Sacrificed scheduled	102

Sex	Group	Animal	Observation	Days
F	1	54	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	1	55	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	1	56	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	1	57	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	1	58	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	1	59	Decubitus, hindlimb, right Sacrificed scheduled	102
F	1	60	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	2	61	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	2	62	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	2	63	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	2	64	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	2	65	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	2	66	General observation, Nothing abnormal detected Sacrificed scheduled	102

Sex	Group	Animal	Observation	Days
F	2	67	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	2	68	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	2	69	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	2	70	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	3	71	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	3	72	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	3	73	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	3	74	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	3	75	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	3	76	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	3	77	Alopecia, body Sacrificed scheduled	102
F	3	78	General observation, Nothing abnormal detected Sacrificed scheduled	102
F	3	79	General observation, Nothing abnormal detected Sacrificed scheduled	102

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Study: 5110299/99125

OBSERVATIONS REPORT - SUMMARY

Print Date: 13-Nov-2001  
Print Time: 08:42:22  
Table : 11A  
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Sex	Group	Animal	Observation
F	3	80	General observation. Nothing abnormal detected
			Sacrificed scheduled

Days  
102  
102

Study: 5110299/99125

## OBSERVATIONS REPORT - SUMMARY

Print Date: 13-Nov-2001  
 Print Time: 08:47:51  
 Table : TIA  
 Page : 17

Sex	Group	Animal	Observation	Days
F	01	81	General observation, Nothing abnormal detected	-5--3
F	01	82	General observation, Nothing abnormal detected	-5--3
F	01	83	General observation, Nothing abnormal detected	-5--3
F	01	84	General observation, Nothing abnormal detected	-5--3
F	01	85	General observation, Nothing abnormal detected	-5--3
F	01	86	General observation, Nothing abnormal detected	-5--3
F	01	87	General observation, Nothing abnormal detected	-5--3
F	01	89	General observation, Nothing abnormal detected	-5--3
F	01	90	General observation, Nothing abnormal detected	-5--3
F	21	91	General observation, Nothing abnormal detected	-5--3
F	21	92	General observation, Nothing abnormal detected	-5--3
F	21	93	General observation, Nothing abnormal detected	-5--3
F	21	94	General observation, Nothing abnormal detected	-5--3
F	21	95	General observation, Nothing abnormal detected	-5--3
F	21	96	General observation, Nothing abnormal detected	-5--3
F	21	97	General observation, Nothing abnormal detected	-5--3
F	21	98	General observation, Nothing abnormal detected	-5--3
F	21	99	General observation, Nothing abnormal detected	-5--3
F	21	100	General observation, Nothing abnormal detected	-5--3
F	31	101	General observation, Nothing abnormal detected	-5--3
F	31	102	General observation, Nothing abnormal detected	-5--3
F	31	103	General observation, Nothing abnormal detected	-5--3
F	31	104	General observation, Nothing abnormal detected	-5--3
F	31	105	General observation, Nothing abnormal detected	-5--3
F	31	106	General observation, Nothing abnormal detected	-5--3
F	31	107	General observation, Nothing abnormal detected	-5--3

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OBSERVATIONS REPORT - SUMMARY

Print Date: 13-Nov-2001  
Print Time: 08:47:51  
Table : IIA  
Page : 18

Study: 5110299/99125

Sex	Group	Animal	Observation	Days
F	31	108	General observation, Nothing abnormal detected	-5--3
F	31	109	General observation, Nothing abnormal detected	-5--3
F	31	110	General observation, Nothing abnormal detected	-5--3

## OBSERVATIONS REPORT - SUMMARY

Print Date: 13-Nov-2001  
 Print Time: 08:48:40  
 Table : ITA  
 Page : 19

Study: 5110299/99125

Sex	Group	Animal	Observation	Days
F	01	81	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	01	82	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	01	83	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	01	84	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	01	85	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	01	86	General observation, Nothing abnormal detected	0(BE)-22(DE)
			Nose, crust formation, red, moderate	
			Found dead	
F	01	87	General observation, Nothing abnormal detected	22(AE)
F	01	88	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	01	89	General observation, Nothing abnormal detected	15(BE)-101(AE)
F	01	90	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	21	91	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	21	92	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	21	93	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	21	94	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	21	95	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	21	96	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	21	97	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	21	98	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	21	99	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	21	100	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	31	101	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	31	102	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	31	103	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	31	104	General observation, Nothing abnormal detected	0(BE)-101(AE)

## OBSERVATIONS REPORT - SUMMARY

Print Date: 13-Nov-2001  
Print Time: 08:48:40  
Table : IIA  
Page : 20

Study: 5110299/99125

Sex	Group	Animal	Observation	Days
F	31	105	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	31	106	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	31	107	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	31	108	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	31	109	General observation, Nothing abnormal detected	0(BE)-101(AE)
F	31	110	General observation, Nothing abnormal detected	0(BE)-101(AE)

Study: 5110299/99125

## OBSERVATIONS REPORT - SUMMARY

Print Date: 13-Nov-2001  
 Print Time: 08:49:46  
 Table : IIA  
 Page : 21

Sex	Group	Animal	Observation	Days
F	01	81	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	01	82	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	01	83	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	01	84	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	01	85	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	01	87	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	01	88	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	01	89	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	01	90	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	21	91	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	21	92	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	21	93	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	21	94	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192

## OBSERVATIONS REPORT - SUMMARY

Print Date: 13-Nov-2001  
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 Table : ITA  
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Study: 5110299/99125

Sex	Group	Animal	Observation	Days
F	21	95	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	21	96	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	21	97	General observation, Nothing abnormal detected Alopecia, Limbs, hind limb, left Sacrificed scheduled	102-137 140-192 192
F	21	98	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	21	99	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	21	100	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	31	101	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	31	102	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	31	103	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	31	104	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	31	105	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	31	106	General observation, Nothing abnormal detected Sacrificed scheduled	102-192 192
F	31	107	General observation, Nothing abnormal detected	102-142

Study: 5110299/99125

## OBSERVATIONS REPORT - SUMMARY

Print Date: 13-Nov-2001  
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Table : IIA  
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Sex	Group	Animal	Observation	Days
F	31	107	Piloerection	143-144
			Reduced care on fur	143-144
			Reduced general condition, moderate	143-144
			Nose, margin, crust formation, dark, moderate	143-144
			Found dead	147
F	31	108	General observation, Nothing abnormal detected	102-192
			Sacrificed scheduled	192
F	31	109	General observation, Nothing abnormal detected	102-192
			Sacrificed scheduled	192
F	31	110	General observation, Nothing abnormal detected	102-192
			Sacrificed scheduled	192

## Study: 5110299/99125

## BODY WEIGHT

	Day -3	Day 0	Day 5	Day 12	Day 19	Day 26	Day 33	Day 40	Day 47
<b>Male, Gr 0 0 mg/m<sup>3</sup></b>									
1	231.0	215.6	217.0	211.4	229.4	239.0	256.3	254.0	273.4
2	231.0	220.0	229.7	230.4	246.7	260.3	276.3	274.9	289.7
3	248.9	242.1	256.2	259.0	273.0	298.9	300.2	320.0	320.0
4	225.0	221.8	231.8	239.9	254.1	270.1	277.4	288.0	288.0
5	232.1	233.7	239.9	240.4	271.1	298.1	304.1	320.7	320.7
6	236.9	230.1	240.4	251.1	263.8	273.7	292.3	309.0	309.0
7	220.3	210.7	209.0	216.3	232.9	242.7	241.9	260.6	260.6
8	244.9	238.2	251.8	265.2	284.3	298.0	325.3	340.1	340.1
9	229.1	215.6	221.4	223.4	227.0	231.2	249.9	255.2	276.4
10	227.5	221.2	227.3	224.6	229.6	235.8	244.0	246.9	262.8
<b>Male, Gr 1 1.5 mg/m<sup>3</sup></b>									
11	234.8	230.3	231.9	245.9	256.8	260.9	280.8	287.6	305.7
12	228.3	227.8	238.3	251.5	257.9	270.2	272.3	285.5	302.3
13	246.3	232.9	243.2	266.5	277.6	293.8	296.8	316.9	316.9
14	218.1	213.1	226.3	235.6	236.5	247.9	256.2	265.5	281.9
15	234.1	229.3	241.3	244.7	257.6	263.4	288.6	304.3	325.6
16	235.1	228.6	243.7	257.4	266.4	279.8	298.6	303.6	323.1
17	216.6	215.5	220.2	228.2	235.1	241.8	253.6	257.4	270.6
18	244.8	235.6	252.8	268.6	283.2	300.5	317.8	320.3	336.5
19	228.3	219.7	226.2	226.0	238.7	248.5	259.8	263.9	275.1
20	225.3	218.9	230.6	236.0	250.6	258.6	270.7	275.4	291.9
<b>Male, Gr 2 3 mg/m<sup>3</sup></b>									
21	230.3	225.5	227.3	234.4	233.9	250.0	269.3	271.8	290.0
22	228.3	220.4	225.1	224.4	236.2	246.0	259.4	267.2	286.6
23	246.0	244.1	261.4	272.8	287.7	292.2	315.2	324.9	345.8
24	212.9	212.0	227.2	224.5	241.7	248.9	270.3	279.1	286.9
25	236.8	229.8	232.4	232.4	249.0	255.7	272.9	280.1	295.8
26	242.8	236.0	246.5	251.4	261.8	276.1	295.7	301.8	305.1
27	217.9	217.3	223.2	218.5	235.1	244.1	259.4	263.0	277.1
28	244.4	245.4	258.8	267.7	284.7	290.8	310.8	319.1	330.8
29	222.0	205.3	213.3	212.4	223.7	231.5	244.7	239.1	258.2
30	225.9	227.6	233.3	244.8	254.6	260.1	270.5	274.0	285.1
<b>Male, Gr 3 8 mg/m<sup>3</sup></b>									
31	233.4	224.2	228.0	234.7	242.8	256.9	276.3	280.1	297.5
32	229.8	228.0	236.4	245.5	242.7	256.0	275.5	278.2	295.4
33	239.2	237.6	248.4	260.5	273.2	281.4	295.5	302.3	315.5
34	217.4	215.0	217.7	222.0	232.9	241.5	251.4	258.1	272.7
35	235.9	235.7	245.7	255.6	257.5	269.2	284.4	294.9	304.4
36	241.9	245.8	255.9	259.9	263.8	268.8	284.0	286.7	300.5
37	229.9	219.9	245.1	225.1	240.9	252.1	267.4	271.1	290.0
38	237.0	226.5	226.9	221.4	232.1	244.2	258.3	261.1	278.9
39	228.7	218.3	221.6	230.6	243.3	249.3	261.1	267.3	283.1
	223.2	219.1	227.8				271.7		284.6

	Day 54	Day 61	Day 68	Day 75	Day 82	Day 89	Day 96	Day 103
<b>Male, Gr 0 0 mg/m³</b>								
1	263.9	253.2	267.0	277.3	280.2	287.2	287.8	290.6
2	289.0	299.3	305.7	317.7	321.7	320.7	330.6	331.8
3	320.0	325.5	329.6	337.6	344.8	342.3	352.9	353.0
4	283.7	285.2	293.2	299.0	305.1	309.7	319.2	320.1
5	323.5	314.0	322.0	333.6	344.3	348.2	357.8	362.9
6	302.0	308.6	316.8	331.9	331.1	340.2	348.7	345.5
7	261.0	265.1	271.0	284.2	293.0	296.9	304.1	307.3
8	343.6	347.4	354.3	367.8	377.4	379.3	387.2	395.3
9	269.3	268.6	267.8	274.1	280.6	279.0	284.9	291.0
10	252.0	257.1	261.6	268.5	279.1	277.5	279.5	276.4
<b>Male, Gr 1 1.5 mg/m³</b>								
11	302.8	301.1	312.7	312.8	311.6	318.5	323.2	329.1
12	310.0	314.4	317.0	320.8	323.5	323.5	337.4	340.4
13	322.9	311.3	329.4	340.7	349.0	345.2	351.3	358.5
14	280.8	282.2	279.8	286.8	289.3	292.2	299.5	303.7
15	332.0	337.0	342.1	348.8	337.2	339.8	353.4	357.5
16	321.0	328.9	337.7	347.1	354.1	349.4	345.7	362.0
17	273.0	271.3	278.3	279.3	277.7	283.9	292.1	292.1
18	343.1	343.6	354.3	361.6	359.3	369.6	372.8	380.3
19	274.7	280.5	283.7	290.0	298.2	295.1	304.4	303.3
20	293.5	296.7	295.5	305.8	307.9	313.0	314.5	321.4
<b>Male, Gr 2 3 mg/m³</b>								
21	288.4	275.6	288.7	297.1	306.4	311.2	317.8	315.8
22	290.1	299.1	298.9	306.2	316.1	320.5	325.3	327.3
23	351.4	360.4	366.7	371.0	378.1	378.1	389.0	386.9
24	296.9	308.8	315.7	323.6	331.0	332.1	336.7	329.9
25	295.9	291.4	300.1	309.5	316.0	321.0	328.3	324.4
26	313.5	318.6	335.2	340.1	347.7	351.8	361.5	363.3
27	279.2	272.1	289.2	295.5	300.4	307.7	315.9	319.0
28	337.7	343.5	333.7	348.5	355.1	357.5	362.2	369.4
29	255.7	251.9	262.6	270.8	277.0	283.3	286.3	288.1
30	290.9	286.3	299.5	305.3	356.5	318.6	328.0	332.7
<b>Male, Gr 3 8 mg/m³</b>								
31	289.6	285.9	295.7	305.7	310.7	314.2	319.4	322.8
32	303.1	308.3	307.6	320.4	326.2	332.3	341.4	343.2
33	323.1	325.6	328.4	337.6	334.5	347.5	352.8	359.1
34	276.4	284.6	286.8	292.7	300.9	305.5	308.8	307.2
35	301.2	301.9	302.8	309.6	318.2	321.3	327.2	329.8
36	306.9	308.3	312.2	327.7	336.6	342.0	346.9	351.8
37	283.0	288.5	295.4	295.4	301.3	311.7	313.9	317.2
38	269.5	273.7	277.4	279.1	280.7	285.3	288.3	293.8
39	284.5	293.7	295.1	300.6	300.7	307.9	310.3	319.4
40	289.8	296.2	306.3	315.1	318.7	324.5	329.1	

## Study: 5110299/99125

## BODY WEIGHT

	Day -5	Day 0	Day 3	Day 10	Day 17	Day 24	Day 31	Day 38	Day 45
<b>Female, Gr 0 0 mg/m<sup>3</sup></b>									
41	163.6	165.5	169.7	171.5	181.0	186.6	194.1	198.0	205.3
42	163.1	165.6	169.4	171.5	171.9	182.5	187.2	191.9	194.3
43	171.5	174.1	175.7	187.7	193.9	203.0	205.0	210.2	215.6
44	156.4	162.2	158.8	168.5	179.1	183.2	186.3	192.8	195.7
45	168.0	173.4	175.6	179.9	190.1	199.0	213.5	211.1	214.5
46	154.0	153.2	151.4	155.6	166.3	172.5	179.3	183.1	183.1
47	162.2	167.5	160.4	170.7	183.0	186.9	195.7	207.0	211.9
48	160.9	173.8	168.5	182.9	198.1	201.9	204.4	213.9	218.6
49	161.1	166.1	165.6	169.4	175.9	186.2	186.3	192.2	192.2
50	167.0	165.2	164.6	168.1	176.8	186.6	193.6	198.2	203.4
<b>Female, Gr 1 1.5 mg/m<sup>3</sup></b>									
51	158.4	166.5	163.8	174.8	177.7	187.7	190.1	193.2	196.0
52	165.7	164.3	169.7	172.0	175.1	184.3	186.8	190.6	192.5
53	175.5	174.2	173.5	176.6	183.6	185.9	198.0	201.4	204.7
54	154.5	158.0	159.4	169.1	176.2	180.5	183.9	190.7	191.6
55	162.9	172.5	175.9	173.1	186.1	195.0	205.4	209.7	212.5
56	156.8	157.4	156.2	158.2	164.4	170.6	173.5	179.4	185.0
57	161.5	167.7	165.6	178.9	183.6	186.3	194.2	196.2	201.9
58	146.7	156.7	155.2	162.3	170.1	175.5	182.2	189.8	189.7
59	163.9	175.3	172.2	180.0	187.7	196.6	198.6	210.8	214.4
60	166.6	174.9	172.9	179.5	187.8	196.4	200.9	203.7	210.8
<b>Female, Gr 2 3 mg/m<sup>3</sup></b>									
61	164.6	167.4	173.9	181.5	185.8	185.1	194.8	197.6	197.0
62	158.3	165.3	164.8	170.4	180.0	183.2	193.3	192.5	200.1
63	171.4	173.4	171.9	179.8	186.8	191.1	194.4	199.1	202.5
64	156.3	163.9	164.4	167.9	174.4	182.9	191.4	191.3	196.4
65	159.3	156.5	153.9	157.7	162.0	164.8	174.8	174.5	177.1
66	160.1	165.3	160.5	167.1	175.1	183.2	183.1	193.8	194.3
67	161.8	164.9	165.8	175.1	179.4	190.5	190.5	195.4	200.8
68	154.2	154.1	157.0	160.3	169.4	175.0	179.7	186.6	188.2
69	161.0	165.5	163.7	172.2	175.8	177.1	181.2	186.1	189.0
70	168.6	169.6	170.4	174.6	179.0	191.5	195.2	199.0	201.1
<b>Female, Gr 3 8 mg/m<sup>3</sup></b>									
71	167.0	174.1	173.4	182.1	187.5	181.9	195.5	196.9	202.2
72	157.6	166.1	161.6	168.4	175.2	180.7	186.0	186.0	188.1
73	162.3	170.7	171.3	178.4	180.4	191.4	195.2	199.3	206.0
74	150.6	161.2	162.0	173.3	179.4	185.2	194.9	198.1	204.8
75	163.4	164.4	166.3	174.0	175.4	186.8	193.0	194.3	196.6
76	161.8	168.4	168.4	170.3	188.3	197.2	198.3	199.0	212.2
77	159.1	162.7	162.3	169.6	182.0	190.2	194.6	198.5	203.6
78	153.0	162.4	162.4	162.4	168.4	176.0	186.1	189.5	190.8
79	164.4	168.3	173.4	183.9	184.3	192.4	196.5	205.1	207.7
80	167.3	175.7	175.5	184.3	191.0	198.8	205.3	211.3	

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	Day 52	Day 59	Day 65	Day 73	Day 80	Day 86	Day 94	Day 101
<b>Female, Gr 0 0 mg/m<sup>3</sup></b>								
41	209.1	222.8	212.8	219.2	223.8	217.5	217.4	216.1
42	199.2	202.3	204.2	213.1	217.0	212.0	215.2	214.7
43	220.0	222.5	229.2	232.5	236.5	238.0	243.2	241.2
44	197.3	196.5	205.4	211.3	212.6	211.7	209.5	214.8
45	215.2	223.2	223.5	229.0	230.7	234.1	232.8	232.8
46	179.6	181.1	185.4	188.6	191.0	194.7	196.2	195.7
47	210.2	212.0	219.5	223.6	226.9	229.3	230.6	229.3
48	216.4	224.2	228.4	231.1	226.3	232.1	234.1	228.0
49	191.6	195.6	193.3	196.5	196.8	195.9	197.6	199.7
50	205.3	212.7	211.1	217.2	219.9	224.8	225.6	226.8
<b>Female, Gr 1 1.5 mg/m<sup>3</sup></b>								
51	197.7	208.7	197.1	205.9	211.1	205.2	212.6	213.4
52	195.9	196.4	196.8	198.8	198.9	198.0	204.0	209.8
53	207.9	212.2	213.3	214.4	221.4	219.2	223.9	226.7
54	192.9	192.4	195.9	199.1	195.5	198.8	202.9	202.5
55	216.0	213.8	212.1	212.1	218.1	219.7	228.1	228.8
56	187.4	190.0	193.6	192.1	192.6	192.8	198.2	199.1
57	205.6	203.8	207.4	208.3	212.0	214.5	217.5	219.8
58	192.1	188.6	195.1	194.3	201.5	199.6	204.5	199.7
59	214.0	210.3	213.6	218.4	215.4	220.4	228.7	223.4
60	212.2	214.4	217.1	223.6	222.6	228.3	230.0	230.0
<b>Female, Gr 2 3 mg/m<sup>3</sup></b>								
61	195.0	207.5	205.2	210.2	206.7	209.3	213.0	209.9
62	206.5	200.2	205.1	210.2	211.9	218.9	219.1	219.8
63	199.3	202.2	206.3	207.9	215.9	215.0	212.0	215.2
64	198.7	198.9	203.7	209.5	212.5	213.9	217.8	221.9
65	178.9	180.2	182.1	184.3	190.5	191.6	191.2	192.9
66	191.7	189.5	200.4	201.8	201.3	205.7	207.7	208.9
67	205.0	206.4	211.7	216.4	218.4	217.6	223.1	225.2
68	189.5	192.1	192.3	194.6	200.6	200.1	202.4	203.0
69	190.7	197.1	198.4	202.2	196.6	203.5	209.1	207.4
70	210.9	213.9	211.1	213.4	222.6	220.9	222.2	223.0
<b>Female, Gr 3 8 mg/m<sup>3</sup></b>								
71	207.4	208.4	213.8	214.5	215.6	213.0	219.1	205.2
72	194.3	195.9	196.1	196.1	198.3	201.0	204.2	204.4
73	207.9	211.5	210.2	210.8	216.3	210.8	223.3	217.1
74	202.1	205.5	203.7	205.7	212.3	208.9	211.7	205.7
75	204.1	202.1	203.7	208.6	212.5	213.0	219.1	221.6
76	216.8	217.4	221.5	225.5	219.7	226.0	237.9	
77	207.9	208.2	214.0	214.5	218.0	213.6	219.6	229.8
78	195.4	195.0	201.2	203.6	204.8	207.5	207.3	211.3
79	210.5	217.6	218.9	220.9	223.9	228.6	226.9	230.8
80	210.6	215.6	217.3	215.9	222.4	224.0	224.2	

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	Day -5	Day 0	Day 3	Day 10	Day 17	Day 24	Day 31	Day 38	Day 45
<b>Female, Gr 01 0 mg/m<sup>3</sup></b>									
81	167.2	174.0	171.8	179.1	187.6	193.8	207.1	208.2	212.5
82	162.8	170.1	170.6	176.6	186.1	191.5	198.7	204.3	203.8
83	168.5	171.6	173.9	180.5	188.2	194.9	197.5	202.3	204.3
84	157.6	162.5	162.9	169.7	171.1	177.4	183.1	187.0	189.7
85	164.5	169.0	169.6	176.1	184.8	189.9	196.3	204.3	204.8
86	159.7	166.6	167.6	170.5	175.6	173.7	179.9	181.2	184.4
87	155.7	155.5	160.7	159.6	167.8	173.7	198.0	201.1	209.9
88	159.8	166.2	168.3	173.9	189.5	193.7	192.1	198.7	201.5
89	169.2	174.8	177.2	181.1	180.0	189.0	192.8	193.0	196.6
<b>Female, Gr 21 3 mg/m<sup>3</sup></b>									
91	164.3	164.9	170.3	168.5	177.6	186.5	190.4	198.1	203.3
92	161.5	164.7	169.6	167.6	177.1	186.5	189.2	197.3	205.7
93	174.6	182.1	180.3	193.7	202.4	209.2	213.6	220.7	220.7
94	156.9	159.5	159.6	170.2	169.4	180.0	188.6	190.6	195.5
95	164.0	168.1	165.1	174.5	177.7	180.7	192.1	190.1	188.8
96	157.3	160.0	159.8	167.2	173.3	178.8	189.2	185.8	187.8
97	158.0	160.9	159.9	165.5	169.7	175.7	180.8	180.2	185.7
98	159.0	158.7	157.2	162.9	167.8	174.9	184.0	185.8	192.1
99	161.4	165.2	162.9	174.2	177.1	186.0	188.3	193.9	199.7
100	174.7	181.8	180.3	188.8	199.3	206.4	211.3	224.1	229.9
<b>Female, Gr 31 8 mg/m<sup>3</sup></b>									
101	166.6	170.8	170.1	173.7	180.5	192.5	199.1	202.5	208.4
102	159.2	162.1	160.8	164.6	172.4	182.3	191.0	195.3	198.1
103	168.3	171.0	171.6	173.4	180.2	191.3	199.2	202.0	206.0
104	152.8	157.1	157.7	160.1	168.2	177.3	182.8	186.6	194.7
105	172.2	179.9	182.3	192.1	202.9	219.3	228.9	231.5	235.3
106	152.8	160.0	161.1	166.4	172.8	181.3	189.8	196.5	210.7
107	155.7	154.1	157.6	161.7	168.2	173.9	178.9	182.4	185.6
108	158.8	161.3	166.5	180.1	185.8	192.1	195.8	199.0	208.5
109	163.4	169.8	170.8	175.5	186.7	193.3	200.8	204.6	200.9
110	165.0	171.0	172.1	180.1	196.8	200.5	200.9	203.7	203.7

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	Day 52	Day 59	Day 65	Day 73	Day 80	Day 86	Day 94	Day 101	Day 108
<b>Female, Gr 01 0 mg/m<sup>3</sup></b>									
81	214.3	216.1	220.3	224.0	227.9	231.3	235.2	230.8	237.7
82	204.8	207.8	213.3	219.6	226.5	224.3	228.0	229.1	238.5
83	207.6	213.9	212.9	216.4	217.4	216.6	220.3	218.8	220.1
84	189.5	194.7	198.9	195.3	200.5	203.6	201.9	205.9	211.8
85	211.1	212.9	217.2	218.7	220.1	222.5	220.0	223.8	230.0
86	192.5	195.9	197.9	203.0	208.2	208.0	212.0	213.1	218.1
87	209.9	213.0	218.9	224.4	226.9	225.3	225.2	228.9	238.5
88	201.0	207.6	213.6	216.3	218.0	217.4	225.0	221.6	234.2
89	198.3	200.8	205.0	207.5	208.0	213.2	216.0	215.1	221.7
<b>Female, Gr 21 3 mg/m<sup>3</sup></b>									
91	199.4	203.2	207.2	214.5	211.3	218.2	217.1	220.5	223.5
92	209.7	215.7	221.3	221.6	225.3	220.1	227.1	233.2	237.9
93	223.5	226.4	234.5	234.0	237.1	235.1	240.0	239.8	243.0
94	198.8	200.6	205.6	202.7	210.0	208.0	210.7	212.0	220.0
95	197.7	195.8	198.6	200.4	201.8	205.7	206.4	209.9	216.9
96	190.6	188.9	191.0	192.9	192.5	195.1	196.4	198.4	200.5
97	185.2	187.9	192.6	196.2	198.0	193.3	194.3	196.2	198.3
98	192.5	194.8	198.8	200.0	200.6	200.6	204.9	207.4	214.2
99	202.5	205.0	208.7	207.4	213.6	214.0	219.9	223.8	226.4
100	232.5	232.2	240.2	248.7	246.8	247.8	254.6	258.5	264.9
<b>Female, Gr 31 8 mg/m<sup>3</sup></b>									
101	207.4	208.5	210.6	213.8	212.5	217.1	222.8	223.9	225.9
102	202.8	199.4	204.4	205.9	211.2	218.8	219.9	218.5	224.1
103	208.6	213.4	217.6	216.0	223.7	222.5	222.8	223.0	229.1
104	192.9	192.6	202.2	204.2	207.3	212.4	217.5	219.4	217.6
105	236.9	242.6	239.1	243.4	254.0	252.7	258.4	255.4	269.1
106	206.2	197.1	204.7	208.7	206.7	216.2	213.5	221.4	221.6
107	188.2	189.7	185.3	187.6	189.6	187.3	193.8	193.8	194.3
108	196.1	197.1	211.3	213.8	215.3	221.4	223.6	224.2	227.2
109	210.9	209.9	214.8	212.8	218.0	223.0	231.2	231.9	231.9
110	207.7	205.7	208.9	214.4	216.4	220.1	220.1	224.3	224.3

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	Day 115	Day 122	Day 129	Day 136	Day 143	Day 150	Day 157	Day 164	Day 171
<b>Female, Gr 01 0 mg/m<sup>3</sup></b>									
81	243.7	246.1	241.4	243.8	253.1	262.5	260.6	267.9	265.9
82	246.2	248.5	253.5	258.7	259.1	259.7	255.4	264.0	266.1
83	228.3	229.3	231.1	233.6	233.4	238.9	224.8	234.6	235.9
84	217.2	219.2	226.4	228.6	227.0	227.4	227.0	231.6	224.7
85	242.4	246.7	251.6	251.1	255.3	259.4	262.4	265.7	268.0
86									
87	226.6	226.3	228.8	232.3	228.5	237.4	238.0	242.6	243.0
88	235.7	238.2	241.0	243.8	245.6	244.1	245.1	244.2	242.6
89	240.1	244.4	239.5	251.7	259.4	264.7	259.8	269.0	265.2
90	229.1	225.4	234.3	229.5	234.0	235.0	234.4	240.8	247.5
<b>Female, Gr 21 3 mg/m<sup>3</sup></b>									
91	229.0	240.7	242.4	242.4	244.4	256.2	252.2	252.4	253.2
92	241.5	239.8	245.8	249.3	253.7	254.3	243.7	250.9	255.0
93	250.3	254.4	252.9	253.8	260.1	260.1	256.3	256.0	265.0
94	224.8	225.5	228.1	234.4	235.6	235.0	234.1	239.0	240.9
95	219.5	225.0	222.4	227.1	228.8	236.1	231.8	232.9	229.3
96	203.1	206.4	206.6	212.0	210.6	214.3	212.4	210.3	216.2
97	202.5	207.7	207.7	217.6	219.1	223.0	218.6	219.8	224.7
98	217.7	218.5	227.0	221.3	234.3	227.0	233.8	238.2	
99	236.1	239.3	238.5	238.5	244.3	245.3	243.0	244.3	249.8
100	263.6	256.2	263.2	269.7	279.3	281.3	265.6	270.3	283.4
<b>Female, Gr 31 8 mg/m<sup>3</sup></b>									
101	230.1	235.7	234.1	235.7	246.1	249.5	245.2	252.4	245.8
102	221.7	230.6	239.2	241.3	239.6	235.5	236.1	241.6	241.7
103	224.9	231.9	242.9	248.7	253.1	245.2	251.0	252.2	252.6
104	224.5	231.0	230.4	232.7	232.5	239.3	234.5	235.6	239.3
105	273.9	275.8	277.9	287.4	284.8	285.2	287.4	292.5	289.5
106	219.6	226.7	230.5	230.8	228.7	227.7	236.5	239.4	234.8
107	185.8	188.7	188.8	191.4	138.5	237.6	245.6	247.9	
108	224.0	237.0	238.9	241.0	238.0	237.6	245.6	262.0	
109	239.9	235.2	242.1	251.2	249.5	255.1	247.6	245.6	245.6
110	229.9	231.1	237.6	240.8	233.5	242.2	245.6		

	Body Weight g	Body Weight g	Body Weight g	Body Weight g
	Day 178	Day 185	Day 191	
Female, Gr 01 0 mg/m <sup>3</sup>				

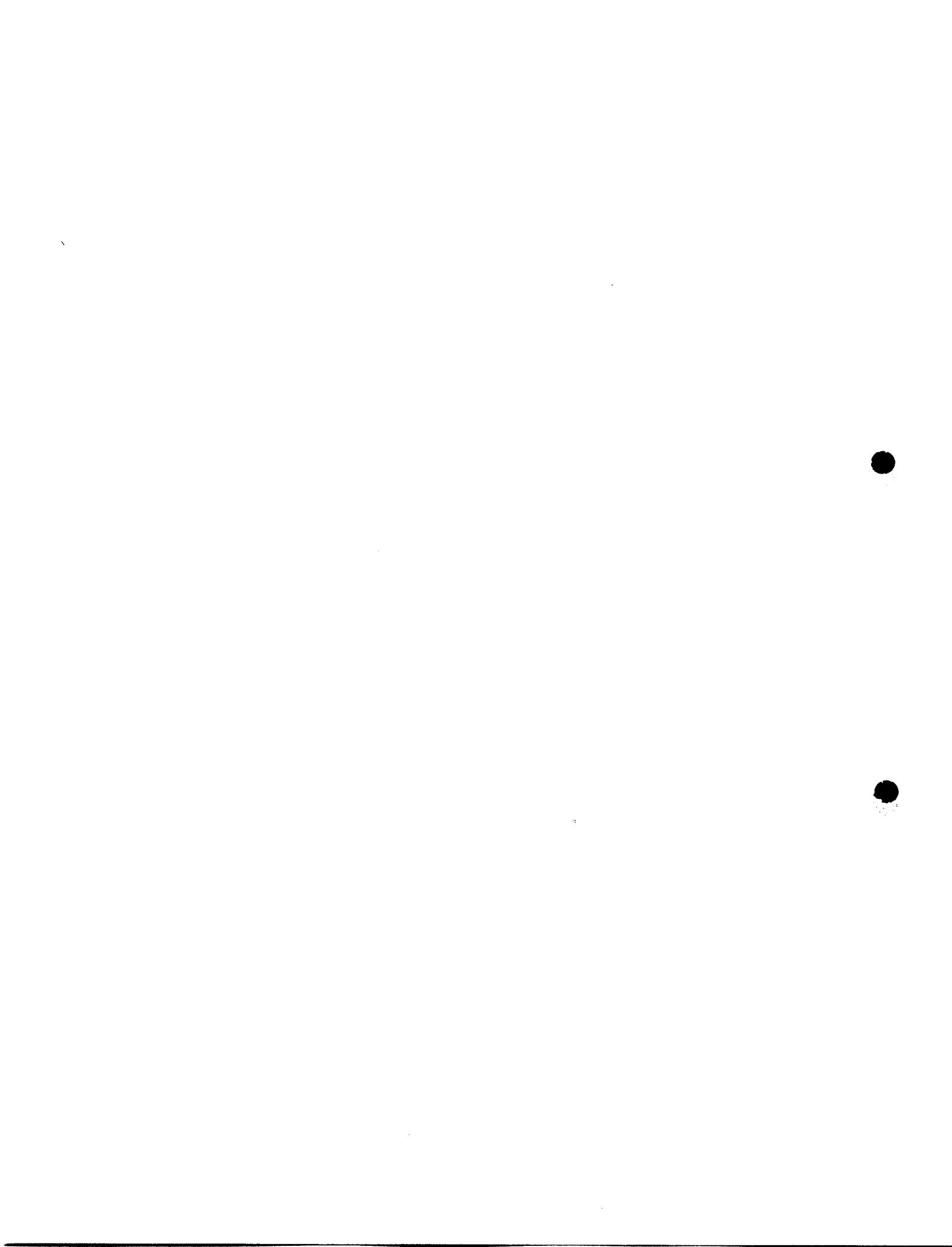
81	257.6	260.9	265.8
82	262.0	266.1	267.5
83	248.2	241.7	242.5
84	232.3	230.8	233.0
85	271.8	277.7	274.0
86			
87	241.9	243.0	251.2
88	241.7	247.4	244.0
89	258.8	262.7	269.1
90	255.0	265.7	262.4

Female, Gr 21 3 mg/m<sup>3</sup>

91	259.0	256.1	256.7
92	253.0	252.0	259.0
93	264.6	261.1	264.7
94	239.7	240.4	243.9
95	231.7	237.7	235.1
96	210.0	210.9	210.1
97	230.2	226.6	226.6
98	235.4	228.5	237.1
99	249.5	250.7	254.0
100	289.2	278.3	278.2

Female, Gr 31 8 mg/m<sup>3</sup>

101	248.0	251.7	256.1
102	244.9	245.9	243.8
103	246.3	252.2	262.4
104	240.8	242.1	243.0
105	287.8	290.3	293.7
106	239.3	242.4	237.4
107			
108	248.6	245.0	240.8
109	256.8	249.8	254.5
110	243.1	249.7	247.2



BASF  
PATHOLOGY REPORT

Diethanolamine: Subchronic Inhalation  
Study in Wistar Rats

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	Liver	Lungs	Kidneys	Testes	Heart
Sex	M					
Dose group	0					
	Term. body weight	g	g	g	g	g
M	305.06	7.74	0.962	1.926	3.158	0.919
SD	34.825	1.39	0.098	0.306	0.497	0.096
n	10	10	10	10	10	10
1	273.6	6.03	0.88	1.59	2.2	0.79
2	309.4	6.71	0.91	2.13	3.48	0.97
3	331.1	7.88	1.05	2.03	3.72	0.94
4	297.2	8.56	1.05	1.85	2.93	0.85
5	338.5	9.49	1.04	2.33	3.35	1.05
6	325.2	9.06	0.99	2.27	3.18	0.97
7	283.	8.76	0.91	1.8	3.25	0.88
8	365.5	8.81	1.09	2.19	3.88	1.07
9	268.9	6.13	0.92	1.51	2.78	0.84
10	258.2	5.97	0.78	1.56	2.81	0.83

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Diethanolamine: Subchronic Inhalation  
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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1		
Sex		M	
Dose group		0	
	Spleen	Brain	Adrenal glands
	g	g	mg
M	0.622	1.906	62.5
SD	0.071	0.086	6.223
n	10	10	10
1	0.63	1.79	53.
2	0.6	1.86	65.
3	0.68	1.99	67.
4	0.6	1.85	70.
5	0.6	2.02	59.
6	0.6	1.94	70.
7	0.54	1.87	62.
8	0.77	2.04	67.
9	0.53	1.83	57.
10	0.67	1.87	55.

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	Liver	Lungs	Kidneys	Testes	Heart
Sex	M					
Dose group	1					
Term. body weight						
	g	g	g	g	g	g
M	311.87	7.552	0.929	1.95	3.163	0.943
SD	28.084	0.688	0.107	0.183	0.394	0.054
n	10	10	10	10	10	10
11	309.6	7.56	0.93	1.73	3.08	0.94
12	321.4	7.49	0.84	1.86	3.19	0.91
13	332.6	8.09	1.01	2.22	3.25	0.95
14	281.1	7.19	0.79	1.92	2.89	0.91
15	333.	7.9	1.03	2.03	3.68	1.
16	334.2	7.86	1.05	2.09	3.63	1.04
17	273.8	7.01	0.95	1.82	2.53	0.89
18	356.7	8.95	1.06	2.23	3.53	1.
19	281.2	6.6	0.79	1.75	3.22	0.88
20	295.1	6.87	0.84	1.85	2.63	0.91

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Diethanolamine: Subchronic Inhalation  
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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1		
Sex		M	
Dose group		1	
	Spleen	Brain	Adrenal glands
	g	g	mg
M	0.616	1.898	60.1
SD	0.084	0.07	7.738
n	10	10	10
11	0.6	1.91	57.
12	0.51	1.89	61.
13	0.69	1.94	59.
14	0.57	1.79	71.
15	0.66	2.03	73.
16	0.77	1.92	63.
17	0.56	1.82	58.
18	0.7	1.92	60.
19	0.55	1.83	51.
20	0.55	1.93	48.

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## PATHOLOGY REPORT

Diethanolamine: Subchronic Inhalation  
Study in Wistar Rats

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## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		F1				
Sex		M				
Dose group		2				
	Term. body weight	Liver	Lungs	Kidneys	Testes	Heart
	g	g	g	g	g	g
M	312.64	7.717	0.934	1.937	3.107	0.949
SD	29.183	0.726	0.086	0.171	0.367	0.104
n	10	10	10	10	10	10
21	294.1	6.94	0.83	1.68	3.41	0.85
22	303.5	7.58	1.02	2.02	3.78	0.97
23	367.4	9.22	1.04	2.28	3.35	1.
24	308.8	7.96	0.92	2.01	2.64	0.95
25	303.2	7.88	0.88	1.89	2.88	0.89
26	332.3	7.64	1.06	1.85	2.98	1.
27	293.8	7.12	0.97	1.99	3.21	0.88
28	347.2	8.11	0.93	2.02	3.26	1.2
29	265.8	6.65	0.82	1.72	2.59	0.87
30	310.3	8.07	0.87	1.91	2.97	0.88

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1		
Sex	M		
Dose group	2		
	Spleen	Brain	Adrenal glands
	g	g	mg
M	0.628	1.909	62.3
SD	0.095	0.071	9.031
n	10	10	10
21	0.69	1.77	53.
22	0.71	1.87	70.
23	0.7	2.02	62.
24	0.47	1.85	63.
25	0.58	1.91	63.
26	0.53	1.98	83.
27	0.62	1.93	58.
28	0.78	1.96	55.
29	0.56	1.89	53.
30	0.64	1.91	63.

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	Liver	Lungs	Kidneys	Testes	Heart
Sex	M					
Dose group	3					
Term. body weight		g	g	g	g	g
M	305.12	7.459	1.	1.921	3.114	0.881
SD	18.055	0.62	0.046	0.138	0.335	0.049
n	10	10	10	10	10	10
31	317.7	8.97	0.98	1.9	3.5	0.87
32	316.6	6.9	1.04	1.74	2.84	0.85
33	333.3	7.97	1.04	2.25	3.59	0.96
34	287.6	7.36	0.99	1.86	3.3	0.9
35	307.1	6.82	0.99	2.04	3.34	0.84
36	324.2	7.36	1.07	1.86	2.81	0.83
37	293.9	7.25	0.99	1.85	3.03	0.91
38	274.7	7.26	0.9	1.93	2.55	0.85
39	294.6	7.17	1.01	1.86	2.92	0.84
40	301.5	7.53	0.99	1.92	3.26	0.96

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1		
Sex		M	
Dose group		3	
	Spleen	Brain	Adrenal glands
	g	g	mg
M	0.62	1.885	60.9
SD	0.076	0.079	5.216
n	10	10	10
31	0.71	1.8	63.
32	0.56	1.93	56.
33	0.77	2.03	60.
34	0.65	1.81	52.
35	0.53	1.95	61.
36	0.58	1.96	66.
37	0.66	1.81	71.
38	0.56	1.82	58.
39	0.61	1.88	61.
40	0.57	1.86	61.

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## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		F1	Lungs	Kidneys	Heart	Spleen
Sex		F				
Dose group		0				
Term. body weight	g	g	g	g	g	g
M	204.83	5.375	0.776	1.381	0.68	0.469
SD	13.696	0.617	0.072	0.058	0.041	0.06
n	10	10	10	10	10	10
41	199.3	5.16	0.81	1.32	0.65	0.52
42	195.1	5.44	0.72	1.37	0.65	0.46
43	225.1	6.15	0.79	1.39	0.76	0.44
44	199.9	5.96	0.86	1.44	0.69	0.4
45	221.	5.48	0.79	1.34	0.71	0.49
46	191.1	5.73	0.85	1.38	0.63	0.46
47	214.1	5.72	0.81	1.35	0.68	0.43
48	214.7	5.21	0.72	1.48	0.72	0.45
49	182.6	3.98	0.62	1.3	0.64	0.43
50	205.4	4.92	0.79	1.44	0.67	0.61

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	
Sex	F	
Dose group	0	
	Brain	Adrenal glands
	g	mg
M	1.808	73.1
SD	0.07	11.752
n	10	10
41	1.8	60.
42	1.82	79.
43	1.82	89.
44	1.91	65.
45	1.8	72.
46	1.65	72.
47	1.86	58.
48	1.76	64.
49	1.86	80.
50	1.8	92.

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## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	Liver	Lungs	Kidneys	Heart	Spleen
Term. body weight	g	g	g	g	g	g
M	195.94	5.14	0.778	1.347	0.683	0.475
SD	10.75	0.714	0.066	0.096	0.042	0.035
n	10	10	10	10	10	10
51	193.5	4.74	0.87	1.33	0.65	0.44
52	189.7	4.52	0.78	1.22	0.67	0.45
53	203.8	4.62	0.72	1.26	0.68	0.46
54	184.9	4.64	0.73	1.2	0.63	0.44
55	205.5	5.95	0.72	1.43	0.67	0.49
56	182.2	4.52	0.9	1.36	0.66	0.44
57	199.7	5.	0.73	1.41	0.73	0.52
58	182.6	5.05	0.83	1.38	0.65	0.52
59	206.4	6.56	0.76	1.5	0.76	0.52
60	211.1	5.8	0.74	1.38	0.73	0.47

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	
Sex	F	
Dose group	1	
	Brain	Adrenal glands
	g	mg
M	1.811	73.6
SD	0.046	10.458
n	10	10
51	1.75	94.
52	1.8	79.
53	1.78	75.
54	1.78	73.
55	1.81	59.
56	1.9	61.
57	1.78	80.
58	1.8	63.
59	1.87	76.
60	1.84	76.

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## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		F1					
Sex		F					
Dose group		2					
	Term. body weight		Liver	Lungs	Kidneys	Heart	Spleen
	g	g	g	g	g	g	g
M	195.68	5.001	0.79	1.333	0.668	0.482	
SD	9.601	0.346	0.071	0.041	0.053	0.07	
n	10	10	10	10	10	10	
61	192.7	5.02	0.87	1.33	0.67	0.61	
62	204.9	4.97	0.81	1.32	0.64	0.58	
63	199.6	4.52	0.74	1.38	0.65	0.47	
64	200.	5.1	0.82	1.32	0.65	0.45	
65	177.3	4.57	0.64	1.26	0.61	0.42	
66	187.5	4.9	0.84	1.32	0.7	0.5	
67	207.9	5.46	0.86	1.36	0.7	0.5	
68	191.6	5.06	0.8	1.41	0.66	0.38	
69	189.8	4.79	0.72	1.31	0.61	0.46	
70	205.5	5.62	0.8	1.32	0.79	0.45	

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1
Sex	F
Dose group	2
Brain	Adrenal glands
	g mg
M	1.819 65.
SD	0.041 7.944
n	10 10
61	1.89 66.
62	1.8 62.
63	1.86 61.
64	1.81 79.
65	1.77 67.
66	1.8 64.
67	1.78 78.
68	1.78 59.
69	1.84 59.
70	1.86 55.

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## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1					
Sex	F					
Dose group	3					
Term. body weight		Liver	Lungs	Kidneys	Heart	Spleen
	g	g	g	g	g	g
M	201.23	6.006	0.854	1.457	0.703	0.522
SD	8.32	0.583	0.04	0.102	0.062	0.068
n	10	10	10	10	10	10
71	203.4	4.86	0.88	1.51	0.65	0.54
72	191.9	5.54	0.81	1.47	0.58	0.59
73	196.7	5.31	0.87	1.44	0.65	0.49
74	190.8	6.05	0.89	1.24	0.68	0.41
75	200.4	6.35	0.84	1.51	0.72	0.49
76	214.9	6.26	0.86	1.6	0.75	0.55
77	209.	6.64	0.79	1.57	0.76	0.62
78	192.1	6.6	0.81	1.44	0.71	0.44
79	209.2	6.3	0.91	1.4	0.77	0.59
80	203.9	6.15	0.88	1.39	0.76	0.5

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	
Sex	F	
Dose group	3	
	Brain	Adrenal glands
	g	mg
M	1.822	71.8
SD	0.058	9.659
n	10	10
71	1.75	64.
72	1.84	57.
73	1.78	61.
74	1.88	75.
75	1.9	84.
76	1.87	80.
77	1.82	80.
78	1.72	80.
79	1.84	63.
80	1.82	74.

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	R1					
Sex	F					
Dose group	0					
Term. body weight		Liver	Lungs	Kidneys	Heart	Spleen
	g	g	g	g	g	g
M	240.833	5.769	0.859	1.414	0.744	0.588
SD	12.291	0.446	0.056	0.101	0.076	0.077
n	9	9	9	9	9	9
81	246.3	6.17	0.95	1.5	0.82	0.72
82	252.7	5.81	0.93	1.53	0.83	0.51
83	232.6	5.28	0.8	1.3	0.65	0.55
84	219.2	5.04	0.81	1.27	0.68	0.6
85	258.7	6.32	0.86	1.42	0.8	0.62
87	233.	5.91	0.84	1.3	0.64	0.57
88	233.4	5.89	0.89	1.42	0.79	0.46
89	248.7	5.35	0.86	1.5	0.7	0.65
90	242.9	6.15	0.79	1.49	0.79	0.61

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	R1
Sex	F
Dose group	O
	Brain      Adrenal glands
	g           mg
M	1.89      75.
SD	0.072     10.735
n	9            9
81	1.87      82.
82	1.77      65.
83	1.82      67.
84	1.88      63.
85	2.          97.
87	1.93      79.
88	1.91      75.
89	1.97      79.
90	1.86      68.

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## ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		R1					
Sex		F					
Dose group		2					
	Term. body weight		Liver	Lungs	Kidneys	Heart	Spleen
	g	g	g	g	g	g	g
M	232.27	5.771	0.842	1.449	0.772	0.549	
SD	18.564	0.672	0.082	0.132	0.094	0.105	
n	10	10	10	10	10	10	
91	240.2	6.24	0.74	1.48	0.79	0.75	
92	242.9	6.04	0.94	1.49	0.97	0.53	
93	251.5	6.27	0.89	1.48	0.81	0.72	
94	226.4	5.24	0.73	1.37	0.67	0.52	
95	225.	5.54	0.78	1.55	0.71	0.57	
96	200.1	4.53	0.83	1.33	0.71	0.43	
97	215.7	5.54	0.88	1.27	0.68	0.49	
98	219.8	5.25	0.84	1.3	0.72	0.52	
99	237.6	6.24	0.81	1.7	0.86	0.5	
100	263.5	6.82	0.98	1.52	0.8	0.46	

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	R1
Sex	F
Dose group	2
	Brain Adrenal glands
	g mg
M	1.896 70.9
SD	0.067 6.79
n	10 10
91	1.81 69.
92	1.94 74.
93	2.03 76.
94	1.87 60.
95	1.89 67.
96	1.82 60.
97	1.86 74.
98	1.97 73.
99	1.88 76.
100	1.89 80.

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	R1					
Sex	F					
Dose group	3					
	Term. body weight	Liver	Lungs	Kidneys	Heart	Spleen
	g	g	g	g	g	g
M	239.667	5.771	0.844	1.528	0.792	0.612
SD	15.129	0.466	0.051	0.102	0.096	0.108
n	9	9	9	9	9	9
101	239.3	5.95	0.81	1.59	0.86	0.52
102	235.6	6.75	0.85	1.76	0.8	0.57
103	245.9	5.26	0.94	1.46	0.75	0.55
104	228.6	5.56	0.83	1.52	0.71	0.8
105	276.2	6.	0.92	1.53	0.79	0.62
106	226.1	5.64	0.8	1.47	1.01	0.66
108	230.6	5.97	0.83	1.52	0.69	0.5
109	241.9	5.23	0.82	1.5	0.75	0.53
110	232.8	5.58	0.8	1.4	0.77	0.76

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ABSOLUTE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	R1
Sex	F
Dose group	3
	Brain      Adrenal glands
	g           mg
M	1.871      78.556
SD	0.073      10.489
n	9            9
101	1.82      62.
102	1.82      88.
103	1.83      79.
104	1.8        68.
105	1.92      96.
106	1.86      75.
108	1.92      80.
109	1.84      73.
110	2.03      86.

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	Liver	Lungs	Kidneys	Testes	Heart
Sex	M					
Dose group	0					
Term. body weight						
	%	%	%	%	%	%
M	100.	2.532	0.316	0.629	1.034	0.302
SD		0.328	0.019	0.048	0.102	0.013
n	10	10	10	10	10	10
1	100.	2.204	0.322	0.581	0.804	0.289
2	100.	2.169	0.294	0.688	1.125	0.314
3	100.	2.38	0.317	0.613	1.124	0.284
4	100.	2.88	0.353	0.622	0.986	0.286
5	100.	2.804	0.307	0.688	0.99	0.31
6	100.	2.786	0.304	0.698	0.978	0.298
7	100.	3.095	0.322	0.636	1.148	0.311
8	100.	2.41	0.298	0.599	1.062	0.293
9	100.	2.28	0.342	0.562	1.034	0.312
10	100.	2.312	0.302	0.604	1.088	0.321

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1		
Sex	M		
Dose group	0		
	Spleen	Brain	Adrenal glands
	%	%	%
M	0.205	0.63	0.021
SD	0.024	0.05	0.002
n	10	10	10
1	0.23	0.654	0.019
2	0.194	0.601	0.021
3	0.205	0.601	0.02
4	0.202	0.622	0.024
5	0.177	0.597	0.017
6	0.185	0.597	0.022
7	0.191	0.661	0.022
8	0.211	0.558	0.018
9	0.197	0.681	0.021
10	0.259	0.724	0.021

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		F1				
Sex		M				
Dose group		1				
	Term. body weight	Liver	Lungs	Kidneys	Testes	Heart
	%	%	%	%	%	%
M	100.	2.423	0.298	0.626	1.013	0.303
SD		0.092	0.023	0.039	0.079	0.016
n	10	10	10	10	10	10
11	100.	2.442	0.3	0.559	0.995	0.304
12	100.	2.33	0.261	0.579	0.993	0.283
13	100.	2.432	0.304	0.667	0.977	0.286
14	100.	2.558	0.281	0.683	1.028	0.324
15	100.	2.372	0.309	0.61	1.105	0.3
16	100.	2.352	0.314	0.625	1.086	0.311
17	100.	2.56	0.347	0.665	0.924	0.325
18	100.	2.509	0.297	0.625	0.99	0.28
19	100.	2.347	0.281	0.622	1.145	0.313
20	100.	2.328	0.285	0.627	0.891	0.308

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1		
Sex	M		
Dose group	1		
	Spleen	Brain	Adrenal glands
	%	%	%
M	0.197	0.612	0.019
SD	0.018	0.041	0.003
n	10	10	10
11	0.194	0.617	0.018
12	0.159	0.588	0.019
13	0.207	0.583	0.018
14	0.203	0.637	0.025
15	0.198	0.61	0.022
16	0.23	0.575	0.019
17	0.205	0.665	0.021
18	0.196	0.538	0.017
19	0.196	0.651	0.018
20	0.186	0.654	0.016

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## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		F1				
Sex		M				
Dose group		2				
	Term. body weight	Liver	Lungs	Kidneys	Testes	Heart
	%	%	%	%	%	%
M	100.	2.47	0.3	0.621	0.998	0.304
SD		0.111	0.023	0.041	0.126	0.022
n	10	10	10	10	10	10
21	100.	2.36	0.282	0.571	1.159	0.289
22	100.	2.498	0.336	0.666	1.245	0.32
23	100.	2.51	0.283	0.621	0.912	0.272
24	100.	2.578	0.298	0.651	0.855	0.308
25	100.	2.599	0.29	0.623	0.95	0.294
26	100.	2.299	0.319	0.557	0.897	0.301
27	100.	2.423	0.33	0.677	1.093	0.3
28	100.	2.336	0.268	0.582	0.939	0.346
29	100.	2.502	0.309	0.647	0.974	0.327
30	100.	2.601	0.28	0.616	0.957	0.284

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1		
Sex	M		
Dose group	2		
	Spleen	Brain	Adrenal glands
	%	%	%
M	0.201	0.614	0.02
SD	0.028	0.046	0.003
n	10	10	10
21	0.235	0.602	0.018
22	0.234	0.616	0.023
23	0.191	0.55	0.017
24	0.152	0.599	0.02
25	0.191	0.63	0.021
26	0.159	0.596	0.025
27	0.211	0.657	0.02
28	0.225	0.565	0.016
29	0.211	0.711	0.02
30	0.206	0.616	0.02

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Diethanolamine: Subchronic Inhalation  
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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		F1					
Sex		M					
Dose group		3					
	Term. body weight	Liver	Lungs	Kidneys	Testes	Heart	
	%	%	%	%	%	%	
M	100.	2.449	0.328	0.631	1.021	0.29	
SD		0.198	0.012	0.046	0.096	0.022	
n	10	10	10	10	10	10	
31	100.	2.823	0.308	0.598	1.102	0.274	
32	100.	2.179	0.328	0.55	0.897	0.268	
33	100.	2.391	0.312	0.675	1.077	0.288	
34	100.	2.559	0.344	0.647	1.147	0.313	
35	100.	2.221	0.322	0.664	1.088	0.274	
36	100.	2.27	0.33	0.574	0.867	0.256	
37	100.	2.467	0.337	0.629	1.031	0.31	
38	100.	2.643	0.328	0.703	0.928	0.309	
39	100.	2.434	0.343	0.631	0.991	0.285	
40	100.	2.498	0.328	0.637	1.081	0.318	

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1		
Sex		M	
Dose group		3	
	Spleen	Brain	Adrenal glands
	%	%	%
M	0.203	0.619	0.02
SD	0.023	0.025	0.002
n	10	10	10
31	0.223	0.567	0.02
32	0.177	0.61	0.018
33	0.231	0.609	0.018
34	0.226	0.629	0.018
35	0.173	0.635	0.02
36	0.179	0.605	0.02
37	0.225	0.616	0.024
38	0.204	0.663	0.021
39	0.207	0.638	0.021
40	0.189	0.617	0.02

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		F1					
Sex		F					
Dose group		0					
	Term. body weight	Liver	Lungs	Kidneys	Heart	Spleen	
	%	%	%	%	%	%	
M	100.	2.624	0.38	0.676	0.332	0.23	
SD		0.262	0.037	0.044	0.01	0.032	
n	10	10	10	10	10	10	
41	100.	2.589	0.406	0.662	0.326	0.261	
42	100.	2.788	0.369	0.702	0.333	0.236	
43	100.	2.732	0.351	0.618	0.338	0.195	
44	100.	2.981	0.43	0.72	0.345	0.2	
45	100.	2.48	0.357	0.606	0.321	0.222	
46	100.	2.998	0.445	0.722	0.33	0.241	
47	100.	2.672	0.378	0.631	0.318	0.201	
48	100.	2.427	0.335	0.689	0.335	0.21	
49	100.	2.18	0.34	0.712	0.35	0.235	
50	100.	2.395	0.385	0.701	0.326	0.297	

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	
Sex	F	
Dose group	0	
	Brain	Adrenal glands
	%	%
M	0.886	0.036
SD	0.068	0.006
n	10	10
41	0.903	0.03
42	0.933	0.04
43	0.809	0.04
44	0.955	0.033
45	0.814	0.033
46	0.863	0.038
47	0.869	0.027
48	0.82	0.03
49	1.019	0.044
50	0.876	0.045

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## RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		F1				
Sex		F				
Dose group		1				
	Term. body weight	Liver	Lungs	Kidneys	Heart	Spleen
	%	%	%	%	%	%
M	100.	2.618	0.399	0.688	0.349	0.243
SD		0.275	0.051	0.047	0.015	0.019
n	10	10	10	10	10	10
51	100.	2.45	0.45	0.687	0.336	0.227
52	100.	2.383	0.411	0.643	0.353	0.237
53	100.	2.267	0.353	0.618	0.334	0.226
54	100.	2.509	0.395	0.649	0.341	0.238
55	100.	2.895	0.35	0.696	0.326	0.238
56	100.	2.481	0.494	0.746	0.362	0.241
57	100.	2.504	0.366	0.706	0.366	0.26
58	100.	2.766	0.455	0.756	0.356	0.285
59	100.	3.178	0.368	0.727	0.368	0.252
60	100.	2.748	0.351	0.654	0.346	0.223

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	
Sex	F	
Dose group	1	
	Brain	Adrenal glands
	%	%
M	0.927	0.038
SD	0.057	0.005
n	10	10
51	0.904	0.049
52	0.949	0.042
53	0.873	0.037
54	0.963	0.039
55	0.881	0.029
56	1.043	0.033
57	0.891	0.04
58	0.986	0.035
59	0.906	0.037
60	0.872	0.036

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		F1					
Sex		F					
Dose group		2					
	Term. body weight		Liver	Lungs	Kidneys	Heart	Spleen
		%	%	%	%	%	%
M	100.		2.556	0.404	0.682	0.342	0.246
SD			0.131	0.03	0.031	0.023	0.034
n	10		10	10	10	10	10
61	100.		2.605	0.451	0.69	0.348	0.317
62	100.		2.426	0.395	0.644	0.312	0.283
63	100.		2.265	0.371	0.691	0.326	0.235
64	100.		2.55	0.41	0.66	0.325	0.225
65	100.		2.578	0.361	0.711	0.344	0.237
66	100.		2.613	0.448	0.704	0.373	0.267
67	100.		2.626	0.414	0.654	0.337	0.241
68	100.		2.641	0.418	0.736	0.344	0.198
69	100.		2.524	0.379	0.69	0.321	0.242
70	100.		2.735	0.389	0.642	0.384	0.219

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	
Sex	F	
Dose group	2	
	Brain	Adrenal glands
	%	%
M	0.931	0.033
SD	0.046	0.004
n	10	10
61	0.981	0.034
62	0.878	0.03
63	0.932	0.031
64	0.905	0.04
65	0.998	0.038
66	0.96	0.034
67	0.856	0.038
68	0.929	0.031
69	0.969	0.031
70	0.905	0.027

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		F1					
Sex		F					
Dose group		3					
Term. body weight		Liver	Lungs	Kidneys	Heart	Spleen	
	%	%	%	%	%	%	
M	100.	2.987	0.425	0.724	0.349	0.259	
SD		0.291	0.024	0.041	0.024	0.029	
n	10	10	10	10	10	10	
71	100.	2.389	0.433	0.742	0.32	0.265	
72	100.	2.887	0.422	0.766	0.302	0.307	
73	100.	2.7	0.442	0.732	0.33	0.249	
74	100.	3.171	0.466	0.65	0.356	0.215	
75	100.	3.169	0.419	0.753	0.359	0.245	
76	100.	2.913	0.4	0.745	0.349	0.256	
77	100.	3.177	0.378	0.751	0.364	0.297	
78	100.	3.436	0.422	0.75	0.37	0.229	
79	100.	3.011	0.435	0.669	0.368	0.282	
80	100.	3.016	0.432	0.682	0.373	0.245	

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	F1	
Sex	F	
Dose group	3	
	Brain	Adrenal glands
	%	%
M	0.907	0.036
SD	0.043	0.005
n	10	10
71	0.86	0.031
72	0.959	0.03
73	0.905	0.031
74	0.985	0.039
75	0.948	0.042
76	0.87	0.037
77	0.871	0.038
78	0.895	0.042
79	0.88	0.03
80	0.893	0.036

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		R1					
Sex		F					
Dose group		0					
Term. body weight			Liver	Lungs	Kidneys	Heart	Spleen
	%		%	%	%	%	%
M	100.		2.396	0.357	0.587	0.309	0.244
SD			0.143	0.021	0.026	0.025	0.031
n	9		9	9	9	9	9
81	100.		2.505	0.386	0.609	0.333	0.292
82	100.		2.299	0.368	0.605	0.328	0.202
83	100.		2.27	0.344	0.559	0.279	0.236
84	100.		2.299	0.37	0.579	0.31	0.274
85	100.		2.443	0.332	0.549	0.309	0.24
87	100.		2.536	0.361	0.558	0.275	0.245
88	100.		2.524	0.381	0.608	0.338	0.197
89	100.		2.151	0.346	0.603	0.281	0.261
90	100.		2.532	0.325	0.613	0.325	0.251

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	R1	
Sex	F	
Dose group	0	
	Brain	Adrenal glands
	%	%
M	0.786	0.031
SD	0.046	0.004
n	9	9
81	0.759	0.033
82	0.7	0.026
83	0.782	0.029
84	0.858	0.029
85	0.773	0.037
87	0.828	0.034
88	0.818	0.032
89	0.792	0.032
90	0.766	0.028

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group		R1					
Sex		F					
Dose group		2					
	Term. body weight		Liver	Lungs	Kidneys	Heart	Spleen
		%	%	%	%	%	%
M	100.		2.479	0.364	0.625	0.333	0.236
SD			0.124	0.035	0.048	0.031	0.039
n	10		10	10	10	10	10
91	100.		2.598	0.308	0.616	0.329	0.312
92	100.		2.487	0.387	0.613	0.399	0.218
93	100.		2.493	0.354	0.588	0.322	0.286
94	100.		2.314	0.322	0.605	0.296	0.23
95	100.		2.462	0.347	0.689	0.316	0.253
96	100.		2.264	0.415	0.665	0.355	0.215
97	100.		2.568	0.408	0.589	0.315	0.227
98	100.		2.389	0.382	0.591	0.328	0.237
99	100.		2.626	0.341	0.715	0.362	0.21
100	100.		2.588	0.372	0.577	0.304	0.175

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	R1	
Sex	F	
Dose group	2	
	Brain	Adrenal glands
	%	%
M	0.82	0.031
SD	0.06	0.002
n	10	10
91	0.754	0.029
92	0.799	0.03
93	0.807	0.03
94	0.826	0.027
95	0.84	0.03
96	0.91	0.03
97	0.862	0.034
98	0.896	0.033
99	0.791	0.032
100	0.717	0.03

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	R1					
Sex	F					
Dose group	3					
Term. body weight		Liver	Lungs	Kidneys	Heart	Spleen
	%	%	%	%	%	%
M	100.	2.415	0.353	0.639	0.332	0.257
SD		0.236	0.016	0.055	0.049	0.052
n	9	9	9	9	9	9
101	100.	2.486	0.338	0.664	0.359	0.217
102	100.	2.865	0.361	0.747	0.34	0.242
103	100.	2.139	0.382	0.594	0.305	0.224
104	100.	2.432	0.363	0.665	0.311	0.35
105	100.	2.172	0.333	0.554	0.286	0.224
106	100.	2.494	0.354	0.65	0.447	0.292
108	100.	2.589	0.36	0.659	0.299	0.217
109	100.	2.162	0.339	0.62	0.31	0.219
110	100.	2.397	0.344	0.601	0.331	0.326

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RELATIVE WEIGHTS - INDIVIDUAL VALUES

Sacrifice group	R1	
Sex	F	
Dose group	3	
	Brain	Adrenal glands
	%	%
M	0.783	0.033
SD	0.053	0.004
n	9	9
101	0.761	0.026
102	0.772	0.037
103	0.744	0.032
104	0.787	0.03
105	0.695	0.035
106	0.823	0.033
108	0.833	0.035
109	0.761	0.03
110	0.872	0.037

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	0
Animal	1

General Information

Sex : Male  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
                  104 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver  
- Kupffer cell granuloma(s), grade 2.  
All other organs examined without microscopic findings

Animal 2

General Information

Sex : Male  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
                  104 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver  
- Kupffer cell granuloma(s), grade 2.  
Lungs  
- Isolated subendothelial deposit(s) of calcium in pulmonary artery.  
All other organs examined without microscopic findings

Animal 3

General Information

Sex : Male  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
                  104 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	0
cont. Animal	3

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

Larynx, level I

- Inflammatory cells, submucosal, grade 2.

Lungs

- Foam cell accumulations in alveoli, grade 1.

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

Animal	4
--------	---

General Information

Sex : Male

Dose group : 0 (0 mg/m<sup>3</sup>)

Sacrifice group : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 2.
- Fat storage in hepatocytes, grade 3.

All other organs examined without microscopic findings

Animal	5
--------	---

General Information

Sex : Male

Dose group : 0 (0 mg/m<sup>3</sup>)

Sacrifice group : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.
- Fat storage in hepatocytes, grade 2.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	0
Animal	6

General Information

Sex : Male  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.
- Fat storage in hepatocytes, grade 1.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

Animal

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General Information

Sex : Male  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.
- Fat storage in hepatocytes, grade 2.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

Animal

8

General Information

Sex : Male  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
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1 day after end of exposure

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	0
cont. Animal	8

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

Animal	9
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General Information

Sex : Male  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
                  104 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

Animal	10
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General Information

Sex : Male  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
                  104 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

Larynx, level I

- Inflammatory cells, submucosal, grade 1.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

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PATHOLOGY REPORT

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	1
Animal	11

General Information

Sex : Male  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	12
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General Information

Sex : Male  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	13
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General Information

Sex : Male  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	14
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General Information

Sex : Male  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
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1 day after end of exposure

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SINGLE ANIMAL SHEET

	Sacrifice group	F1
	Sex	M
	Dose group	1
	cont. Animal	14

Macroscopy

Testes

- Organ size reduced, right side, slight, weight 1.15 g.

All other organs without macroscopic findings.

Microscopy

Testes

- Gross lesion(s) evaluated histopathologically.
- Tubular atrophy, multifocal/focal, unilateral, grade 2, correlates to gross lesion organ size reduced.

All other organs examined without microscopic findings

	Animal	15
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General Information

Sex : Male  
 Dose group : 1 (1,5 mg/m<sup>3</sup>)  
 Sacrifice group : Final sacrifice group  
 Necropsy status : Planned sacrifice  
 Date of death : Jun/28/2001  
                   104 days after start of exposure  
                   1 day after end of exposure

Macroscopy

Liver

- Focus, left lateral lobe, on the margin, diameter 3.0 mm, yellow.

Epididymides

- Abscess, left side, diameter 8.0 mm, partly yellow.

All other organs without macroscopic findings.

Microscopy

Liver

- Gross lesion(s) evaluated histopathologically.
- Focal necrosis with inflammatory reaction and bile duct proliferation, correlates to gross lesion focus.

Epididymides

- Gross lesion(s) evaluated histopathologically.
- Sperma granuloma, unilateral, correlates to gross lesion abscess.

All other organs examined without microscopic findings

	Animal	16
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General Information

Sex : Male  
 Dose group : 1 (1,5 mg/m<sup>3</sup>)  
 Sacrifice group : Final sacrifice group  
 Necropsy status : Planned sacrifice  
 Date of death : Jun/28/2001  
                   104 days after start of exposure  
                   1 day after end of exposure

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	1
cont. Animal	16

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	17
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General Information

Sex : Male  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Testes

- Focus, left side, diameter 4.0 mm, red.

All other organs without macroscopic findings.

Microscopy

Testes

- Gross lesion(s) evaluated histopathologically.

- Congestion, unilateral, correlates to gross lesion focus.

All other organs examined without microscopic findings

Animal	18
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General Information

Sex : Male  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	19
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General Information

Sex : Male  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	1
cont. Animal	19

Macroscopy

Animal without particular findings.

Microscopy

Larynx, level I

- Inflammatory cells, submucosal, grade 1.

All other organs examined without microscopic findings

Animal	20
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General Information

Sex : Male

Dose group : 1 (1,5 mg/m<sup>3</sup>)

Sacrifice group : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : Jun/28/2001

104 days after start of exposure

1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

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SINGLE ANIMAL SHEET

	Sacrifice group	F1
	Sex	M
	Dose group	2
	Animal	21

General Information

Sex : Male  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Liver  
- Focus, right medial lobe, diameter 4.0 mm, organlike color, surface raised.  
All other organs without macroscopic findings.

Microscopy

Liver  
- Gross lesion(s) evaluated histopathologically.  
- Focal fibrosis (capsule) with subcapsular bile duct proliferations,  
correlates to gross lesion focus.

Larynx, level I

- Metaplasia, squamous.

All other organs examined without microscopic findings

Animal	22
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General Information

Sex : Male  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	23
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General Information

Sex : Male  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
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1 day after end of exposure

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	2
cont. Animal	23

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

24

General Information

Sex : Male  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Kidneys

- Retraction, right side, diameter 2.0 mm.

All other organs without macroscopic findings.

Microscopy

Larynx, level I  
- Metaplasia, squamous.

Kidneys

- Gross lesion(s) evaluated histopathologically.  
- Chronic interstitial nephritis, focal (subcapsular), grade 2, correlates to gross lesion retraction.

All other organs examined without microscopic findings

Animal

25

General Information

Sex : Male  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

26

General Information

Sex : Male  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
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1 day after end of exposure

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	2
cont. Animal	26

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

27

General Information

Sex : Male  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

28

General Information

Sex : Male  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Skin

- Sparse hair, in the anogenital region and on the hindleg left side.

All other organs without macroscopic findings.

Microscopy

Skin

- No histopathologic correlate to gross lesion(s). No histopathologic finding noted.

All other organs examined without microscopic findings

Animal

29

General Information

Sex : Male  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
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1 day after end of exposure

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	2
cont. Animal	29

Macroscopy

Testes

- Focus, left side, few (2-5), diameter 2.0 mm, white.

All other organs without macroscopic findings.

Microscopy

Testes

- Gross lesion(s) evaluated histopathologically.
- Tubular atrophy, multifocal/focal, unilateral, grade 2, correlates to gross lesion focus.
- Calcification, tubular, focal, grade 1, correlates to gross lesion focus.

All other organs examined without microscopic findings

Animal	30
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General Information

Sex : Male

Dose group : 2 (3 mg/m<sup>3</sup>)

Sacrifice group : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : Jun/28/2001

104 days after start of exposure

1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Larynx, level I

- Metaplasia, squamous.

All other organs examined without microscopic findings

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	3
Animal	31

General Information

Sex : Male  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Epididymides  
- Enlarged, left side, slight.  
All other organs without macroscopic findings.

Microscopy

Larynx, level I  
- Metaplasia, squamous.  
- Inflammatory cells, submucosal, grade 3.  
Lungs  
- Isolated subendothelial deposit(s) of calcium in pulmonary artery.  
Epididymides  
- Gross lesion(s) evaluated histopathologically.  
- Sperma granuloma, unilateral, correlates to gross lesion enlarged.  
All other organs examined without microscopic findings

Animal	32
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General Information

Sex : Male  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver  
- Kupffer cell granuloma(s), grade 1.  
Larynx, level I  
- Metaplasia, squamous.  
Larynx, level II  
- Metaplasia, squamous.  
Lungs  
- Isolated subendothelial deposit(s) of calcium in pulmonary artery.  
All other organs examined without microscopic findings

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SINGLE ANIMAL SHEET

	Sacrifice group	\	F1
	Sex		M
	Dose group		3
	Animal		33

General Information

Sex : Male  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 2.  
Larynx, level I  
- Metaplasia, squamous.  
- Inflammatory cells, submucosal, grade 2.

All other organs examined without microscopic findings

	Animal	34
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General Information

Sex : Male  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
104 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 2.  
- Fat storage in hepatocytes, grade 2.

Larynx, level I

- Metaplasia, squamous.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

	Animal	35
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General Information

Sex : Male  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	3
cont. Animal	35

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

Larynx, level I

- Metaplasia, squamous.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

Animal

36

General Information

Sex : Male  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
                  104 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

Larynx, level I

- Metaplasia, squamous.

Larynx, level II

- Metaplasia, squamous.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

Animal

37

General Information

Sex : Male  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/28/2001  
                  104 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	3
cont. Animal	37

Microscopy

Liver

- Kupffer cell granuloma(s), grade 2.

Larynx, level I

- Metaplasia, squamous.

- Inflammatory cells, submucosal, grade 2.

Lungs

- Focus/foci of microgranulomatous inflammation, grade 1.

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

Animal	38
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General Information

Sex : Male

Dose group : 3 (8 mg/m<sup>3</sup>)

Sacrifice group : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : Jun/28/2001

104 days after start of exposure

1 day after end of exposure

Macroscopy

Testes

- Organ size reduced, right side, slight, weight 1.05 g.

All other organs without macroscopic findings

Microscopy

Liver

- Kupffer cell granuloma(s), grade 2.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

Testes

- Gross lesion(s) evaluated histopathologically."

- Tubular atrophy, multifocal/focal, grade 2, correlates to gross lesion organ size reduced.

All other organs examined without microscopic findings

Animal	39
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General Information

Sex : Male

Dose group : 3 (8 mg/m<sup>3</sup>)

Sacrifice group : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : Jun/28/2001

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	M
Dose group	3
cont. Animal	39

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

Larynx, level I

- Metaplasia, squamous.

Lungs

- Foam cell accumulations in alveoli, grade 1.

All other organs examined without microscopic findings

General Information

Sex : Male

Dose group : 3 (8 mg/m<sup>3</sup>)

Sacrifice group : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : Jun/28/2001

104 days after start of exposure

1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

Larynx, level I

- Metaplasia, squamous.

Lungs

- Foam cell accumulations in alveoli, grade 2.

- Focus/foci of microgranulomatous inflammation, grade 1.

All other organs examined without microscopic findings

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SINGLE ANIMAL SHEET

	Sacrifice group	F1
	Sex	F
	Dose group	0
	Animal	41

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.
- Fat storage in hepatocytes, grade 1.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

Animal

42

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.
- Fat storage in hepatocytes, grade 2.

Lungs

- Foam cell accumulations in alveoli, grade 1.

All other organs examined without microscopic findings

Animal

43

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

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Diethanolamine: Subchronic Inhalation  
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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	F
Dose group	0
cont. Animal	43

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.
- Fat storage in hepatocytes, grade 3.

Larynx, level I

- Inflammatory cells, submucosal, grade 1.

All other organs examined without microscopic findings

Animal	44
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General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
                  102 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.
- Fat storage in hepatocytes, grade 1.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

Animal	45
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General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
                  102 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 2.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

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SINGLE ANIMAL SHEET

	Sacrifice group	F1
	Sex	F
	Dose group	0
	Animal	46

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

All other organs examined without microscopic findings

Animal

47

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

- Fat storage in hepatocytes, grade 2.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

Animal

48

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Skin

- Sparse hair, in the side region.

All other organs without macroscopic findings.

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PATHOLOGY REPORT

Diethanolamine: Subchronic Inhalation  
Study in Wistar Rats

IIB- 65  
51I0299/99125  
Feb/27/2002 WEKA  
acopat system

SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	F
Dose group	0
cont. Animal	48

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

Skin

- No histopathologic correlate to gross lesion(s). No histopathologic finding noted.

All other organs examined without microscopic findings

Animal	49
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General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
                  102 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 2.
- Fat storage in hepatocytes, grade 2.

All other organs examined without microscopic findings

Animal	50
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General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
                  102 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 2.

All other organs examined without microscopic findings

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## SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	F
Dose group	1
Animal	51

## General Information

Sex : Female  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

## Macroscopy

Animal without particular findings.

## Microscopy

All organs examined without pathologic findings.

Animal

52

## General Information

Sex : Female  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

## Macroscopy

Animal without particular findings.

## Microscopy

All organs examined without pathologic findings.

Animal

53

## General Information

Sex : Female  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

## Macroscopy

Animal without particular findings.

## Microscopy

All organs examined without pathologic findings.

Animal

54

## General Information

Sex : Female  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	F
Dose group	1
cont. Animal	54

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	55
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General Information

Sex : Female  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
                  102 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	56
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General Information

Sex : Female  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
                  102 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	57
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General Information

Sex : Female  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
                  102 days after start of exposure  
                  1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

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SINGLE ANIMAL SHEET

	Sacrifice group	F1
	Sex	F
	Dose group	1
	Animal	58

General Information

Sex : Female  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

	Animal	59
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General Information

Sex : Female  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Ovaries

- Cyst, left side, diameter 6.0 mm.

Skin

- Decubitus, on the hindleg right side, diameter 5.0 mm, surface scabby.

All other organs without macroscopic findings.

Microscopy

Ovaries

- Gross lesion(s) evaluated histopathologically.

- Cyst(s), unilateral, correlates to gross lesion cyst.

Skin

- Gross lesion(s) evaluated histopathologically.

- Chronic dermatitis with diffuse epidermal hyperplasia and hyperkeratosis, correlates to gross lesion decubitus.

All other organs examined without microscopic findings

	Animal	60
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General Information

Sex : Female  
Dose group : 1 (1,5 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
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1 day after end of exposure

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SINGLE ANIMAL SHEET

	Sacrifice group	F1
	Sex	F
	Dose group	1
	cont. Animal	60

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	F
Dose group	2
Animal	61

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

62

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

63

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

64

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	F
Dose group	2
cont. Animal	64

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

65

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

66

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Liver

- Focal constriction, by diaphragmic herniation, between left medial lobe and right medial lobe, diameter 5.0 mm.

All other organs without macroscopic findings.

Microscopy

Liver

- Gross lesion(s) evaluated histopathologically.

- Focal fibrosis (capsule), correlates to gross lesion focal constriction.

All other organs examined without microscopic findings

Animal

67

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

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	Sacrifice group	F1
	Sex	F
	Dose group	2
	cont. Animal	67

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

68

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

69

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

70

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

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## SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	F
Dose group	3
Animal	71

## General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

## Macroscopy

Animal without particular findings.

## Microscopy

## Liver

- Kupffer cell granuloma(s), grade 1.

All other organs examined without microscopic findings

Animal	72
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## General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

## Macroscopy

Animal without particular findings.

## Microscopy

## Liver

- Kupffer cell granuloma(s), grade 1.  
- Fat storage in hepatocytes, grade 2.

## Larynx, level I

- Metaplasia, squamous.

All other organs examined without microscopic findings

Animal	73
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## General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

## Macroscopy

Animal without particular findings.

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	F
Dose group	3
cont. Animal	73

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.

Larynx, level I

- Metaplasia, squamous.

All other organs examined without microscopic findings

Animal 74

General Information

Sex : Female

Dose group : 3 (8 mg/m<sup>3</sup>)

Sacrifice group : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : Jun/29/2001

102 days after start of exposure

1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.
- Fat storage in hepatocytes, grade 2.

Larynx, level I

- Metaplasia, squamous.

- Inflammatory cells, submucosal, grade 2.

Lungs

- Focus/foci of microgranulomatous inflammation, grade 1.

All other organs examined without microscopic findings

Animal 75

General Information

Sex : Female

Dose group : 3 (8 mg/m<sup>3</sup>)

Sacrifice group : Final sacrifice group

Necropsy status : Planned sacrifice

Date of death : Jun/29/2001

102 days after start of exposure

1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.
- Fat storage in hepatocytes, grade 2.

Larynx, level I

- Metaplasia, squamous.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

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Diethanolamine: Subchronic Inhalation  
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SINGLE ANIMAL SHEET

	Sacrifice group	F1
Sex		F
Dose group		3
Sacrifice group		76

General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.
- Fat storage in hepatocytes, grade 1.

Larynx, level I

- Metaplasia, squamous.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

All other organs examined without microscopic findings

	Animal	77
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General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Skin

- Sparse hair, in the side region.

All other organs without macroscopic findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 2.
- Fat storage in hepatocytes, grade 2.

Larynx, level I

- Metaplasia, squamous.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

Skin

- No histopathologic correlate to gross lesion(s). No histopathologic finding noted.

All other organs examined without microscopic findings

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SINGLE ANIMAL SHEET

	Sacrifice group	F1
Sex	Sex	F
Dose group	Dose group	3
	Animal	78

General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Uterus  
- Dilatation, slight.  
All other organs without macroscopic findings.

Microscopy

Liver  
- Kupffer cell granuloma(s), grade 1.  
- Fat storage in hepatocytes, grade 1.  
Larynx, level I  
- Metaplasia, squamous.  
- Inflammatory cells, submucosal, grade 1.  
Uterus  
- Gross lesion(s) evaluated histopathologically.  
- Dilatation, correlates to gross lesion dilation.  
All other organs examined without microscopic findings

Animal 79

General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

Liver  
- Kupffer cell granuloma(s), grade 2.  
- Pigment storage in hepatocytes, grade 3.  
Larynx, level I  
- Metaplasia, squamous.  
All other organs examined without microscopic findings

Animal 80

General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : Final sacrifice group  
Necropsy status : Planned sacrifice  
Date of death : Jun/29/2001  
102 days after start of exposure  
1 day after end of exposure

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SINGLE ANIMAL SHEET

Sacrifice group	F1
Sex	F
Dose group	3
cont. Animal	80

Macroscopy

- Pituitary gland  
- Cyst, diameter 1.0 mm.

All other organs without macroscopic findings.

Microscopy

Liver

- Kupffer cell granuloma(s), grade 1.  
- Fat storage in hepatocytes, grade 2.

Larynx, level I

- Metaplasia, squamous.  
- Inflammatory cells, submucosal, grade 2.

Lungs

- Isolated subendothelial deposit(s) of calcium in pulmonary artery.

Pituitary gland

- No histopathologic correlate to gross lesion(s). No histopathologic finding noted.

All other organs examined without microscopic findings

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SINGLE ANIMAL SHEET

Sacrifice group	R1
Sex	F
Dose group	0
Animal	81

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

82

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

83

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

84

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

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SINGLE ANIMAL SHEET

Sacrifice group	R1
Sex	F
Dose group	0
cont. Animal	84

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

85

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

86

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Spontaneous death  
Date of death : Apr/10/2001  
22 days after start of exposure

Macroscopy

Lungs

- Discoloration, right cranial lobe and right middle lobe and right caudal lobe, diffuse, red.

All other organs without macroscopic findings.

Microscopy

Nasal cavity, level I

- Congestion.

Nasal cavity, level II

- Congestion.

Nasal cavity, level III

- Congestion.

Nasal cavity, level IV

- Congestion.

Lungs

- Gross lesion(s) evaluated histopathologically.

- Congestion, correlates to gross lesion discolored.

All other organs examined without microscopic findings

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SINGLE ANIMAL SHEET

Sacrifice group	R1
Sex	F
Dose group	0
Animal	87

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

88

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
182 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

89

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

90

General Information

Sex : Female  
Dose group : 0 (0 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

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SINGLE ANIMAL SHEET

Sacrifice group	R1
Sex	F
Dose group	0
cont. Animal	90

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

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SINGLE ANIMAL SHEET

	Sacrifice group	R1
	Sex	F
	Dose group	2
	Animal	91

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Liver  
- Cyst, left lateral lobe, diameter 2.0 mm.  
All other organs without macroscopic findings.

Microscopy

Liver  
- Gross lesion(s) evaluated histopathologically.  
- Vascular dilation, correlates to gross lesion cyst.  
No other organs examined.

Animal 92

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

No histologic examination performed.

Animal 93

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

No histologic examination performed.

BASF  
PATHOLOGY REPORT

Diethanolamine: Subchronic Inhalation  
Study in Wistar Rats

IIB- 83  
51I0299/99125  
Feb/27/2002 WEKA  
acopat system

SINGLE ANIMAL SHEET

Sacrifice group	R1
Sex	F
Dose group	2
Animal	94

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
                  192 days after start of exposure  
                  91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

No histologic examination performed.

Animal	95
--------	----

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
                  192 days after start of exposure  
                  91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

No histologic examination performed.

Animal	96
--------	----

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
                  192 days after start of exposure  
                  91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

No histologic examination performed.

Animal	97
--------	----

General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
                  192 days after start of exposure  
                  91 days after end of exposure

BASF

PATHOLOGY REPORTDiethanolamine: Subchronic Inhalation  
Study in Wistar Rats

IIB- 84

51I0299/99125

Feb/27/2002 WEKA  
acopat system

## SINGLE ANIMAL SHEET

Sacrifice group	R1
Sex	F
Dose group	2
cont. Animal	97

## Macroscopy

## Skin

- Sparse hair, on the hindleg left side, diameter 25.0 mm.
- All other organs without macroscopic findings.

## Microscopy

## Skin

- No histopathologic correlate to gross lesion(s). No histopathologic finding noted.
- No other organs examined.

Animal

98

## General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

## Macroscopy

Animal without particular findings.

## Microscopy

No histologic examination performed.

Animal

99

## General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

## Macroscopy

Animal without particular findings.

## Microscopy

No histologic examination performed.

Animal

100

## General Information

Sex : Female  
Dose group : 2 (3 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

BASF  
PATHOLOGY REPORT

Diethanolamine: Subchronic Inhalation  
Study in Wistar Rats

IIB- 85  
51I0299/99125  
Feb/27/2002 WEKA  
acopat system

SINGLE ANIMAL SHEET

Sacrifice group	R1
Sex	F
Dose group	2
cont. Animal	100

Macroscopy

Liver

- Focus, right medial lobe, diameter 4.0 mm, organlike color, surface raised.

Liver lymph node

- Discoloration, red, tissue preserved in cassette.

All other organs without macroscopic findings.

Microscopy

Liver

- Gross lesion(s) evaluated histopathologically.

- Pigment storage in Kupffer cells ( hemosiderosis), grade 3.

- Hemorrhage, focal, correlates to gross lesion focus.

Liver lymph node

- Gross lesion(s) evaluated histopathologically.

- Hemosiderosis, grade 4, correlates to gross lesion discolored.

No other organs examined.

BASF  
PATHOLOGY REPORT

Diethanolamine: Subchronic Inhalation  
Study in Wistar Rats

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5110299/99125

Feb/27/2002 WEKA  
acopat system

SINGLE ANIMAL SHEET

Sacrifice group	R1
Sex	F
Dose group	3
Animal	101

General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

102

General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

103

General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal

104

General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

BASF  
PATHOLOGY REPORT

Diethanolamine: Subchronic Inhalation  
Study in Wistar Rats

IIB- 87  
51I0299/99125  
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acopat system

SINGLE ANIMAL SHEET

Sacrifice group	R1
Sex	F
Dose group	3
cont. Animal	104

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	105
--------	-----

General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	106
--------	-----

General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Planned sacrifice  
Date of death : Sep/27/2001  
192 days after start of exposure  
91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

Animal	107
--------	-----

General Information

Sex : Female  
Dose group : 3 (8 mg/m<sup>3</sup>)  
Sacrifice group : 3 Month Recovery group  
Necropsy status : Spontaneous death  
Date of death : Aug/13/2001  
147 days after start of exposure  
46 days after end of exposure

Macroscopy

Lungs

- Atelectasis.

Kidneys

- Granular surface, severe, clay colored.

All other organs without macroscopic findings.

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PATHOLOGY REPORT 5110299/99125  
 Diethanolamine: Subchronic Inhalation Feb/27/2002 WEKA  
Study in Wistar Rats acopat system

SINGLE ANIMAL SHEET

	Sacrifice group	R1
	Sex	F
	Dose group	3
	cont. Animal	107

Microscopy

Lungs

- No histopathologic correlate to gross lesion(s).
- Congestion, chronic.

Kidneys

- Gross lesion(s) evaluated histopathologically.
  - Glomerulonephropathy, grade 4, correlates to gross lesion granular surface.
- All other organs examined without microscopic findings

	Animal	108
--	--------	-----

General Information

Sex : Female  
 Dose group : 3 (8 mg/m<sup>3</sup>)  
 Sacrifice group : 3 Month Recovery group  
 Necropsy status : Planned sacrifice  
 Date of death : Sep/27/2001  
                   192 days after start of exposure  
                   91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

	Animal	109
--	--------	-----

General Information

Sex : Female  
 Dose group : 3 (8 mg/m<sup>3</sup>)  
 Sacrifice group : 3 Month Recovery group  
 Necropsy status : Planned sacrifice  
 Date of death : Sep/27/2001  
                   192 days after start of exposure  
                   91 days after end of exposure

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.

	Animal	110
--	--------	-----

General Information

Sex : Female  
 Dose group : 3 (8 mg/m<sup>3</sup>)  
 Sacrifice group : 3 Month Recovery group  
 Necropsy status : Planned sacrifice  
 Date of death : Sep/27/2001  
                   192 days after start of exposure  
                   91 days after end of exposure

BASF  
PATHOLOGY REPORT

Diethanolamine: Subchronic Inhalation  
Study in Wistar Rats

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51I0299/99125  
Feb/27/2002 WEKA  
acopat system

SINGLE ANIMAL SHEET

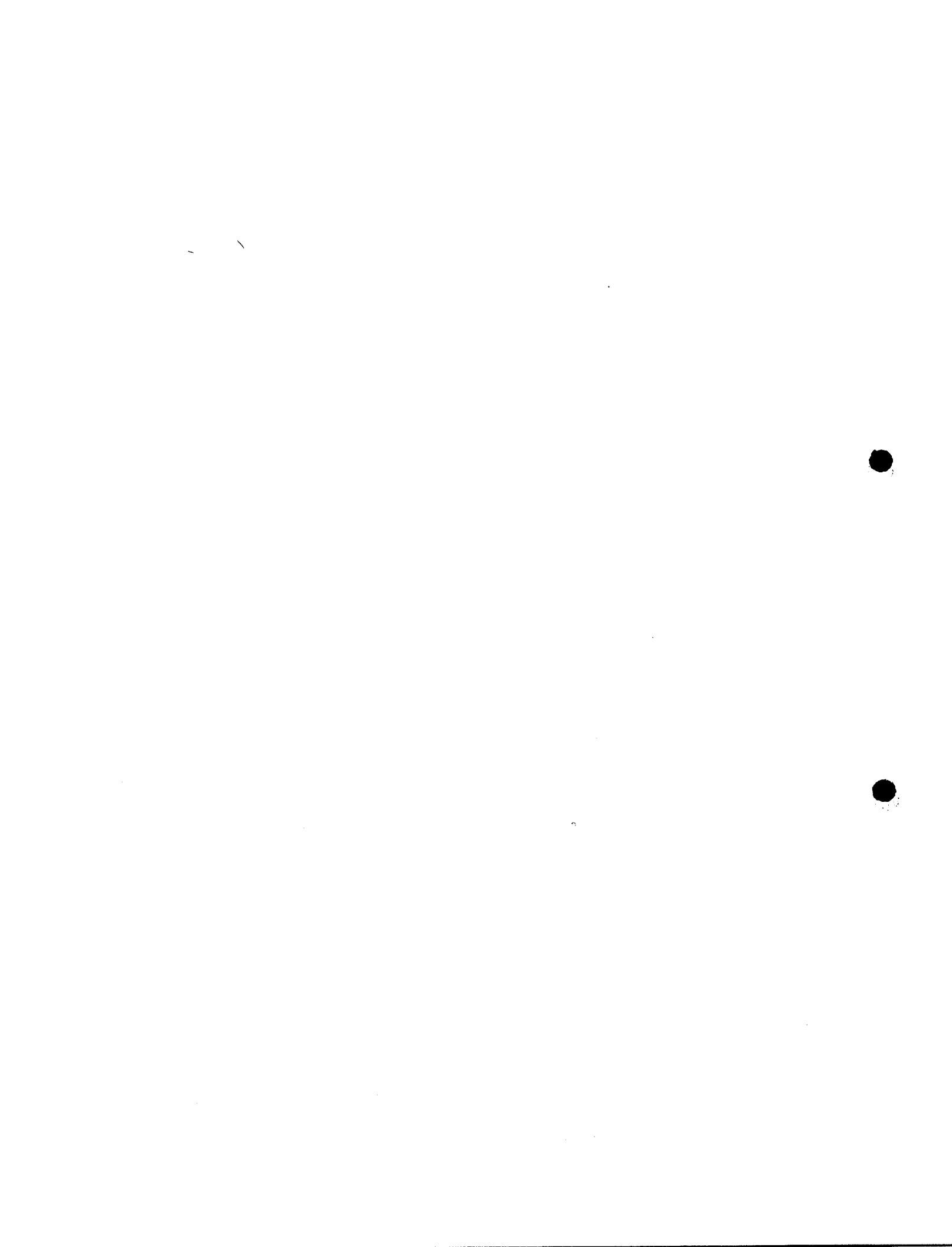
	Sacrifice group	R1
	Sex	F
	Dose group	3
	cont. Animal	110

Macroscopy

Animal without particular findings.

Microscopy

All organs examined without pathologic findings.





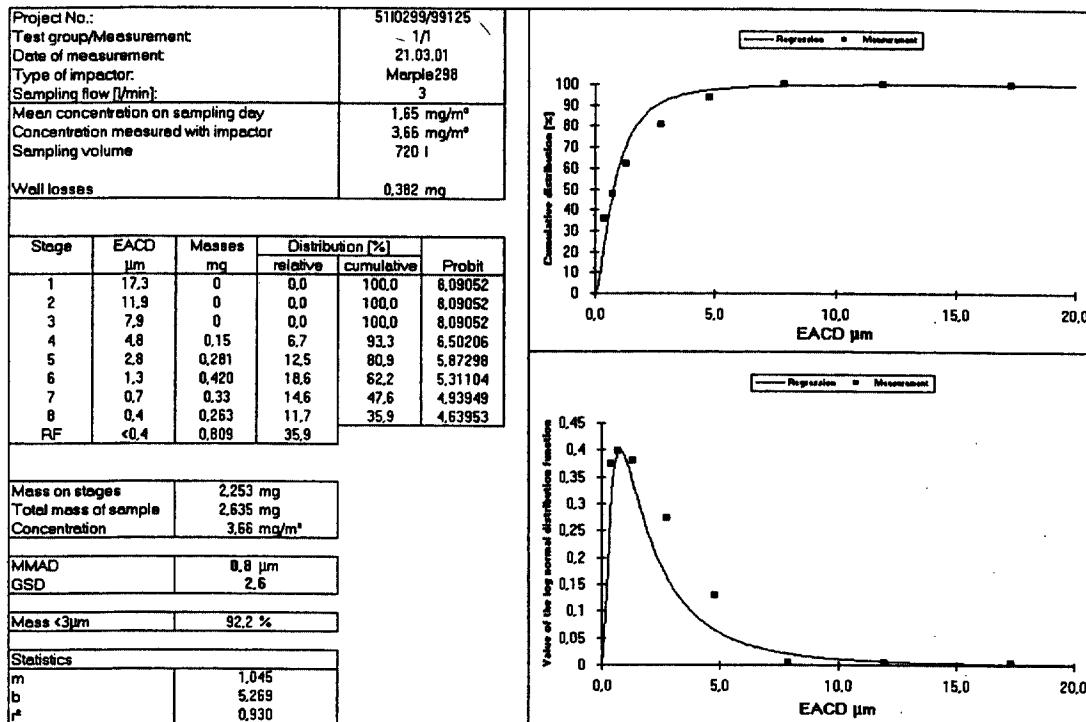




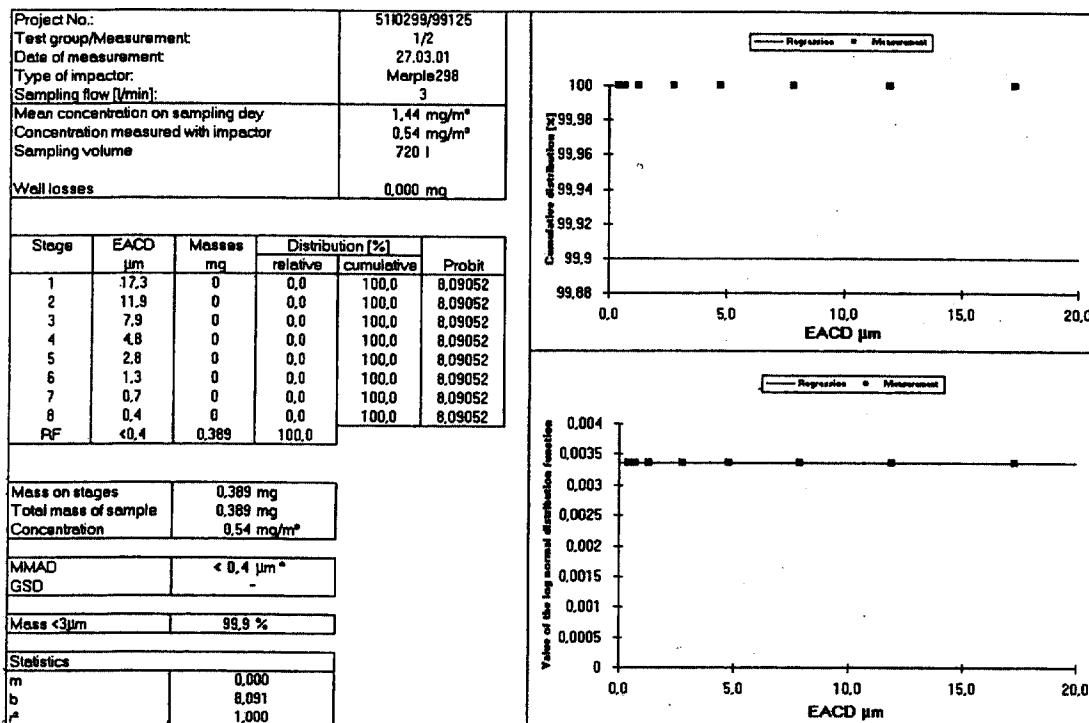


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**Table IIC-005**  
Particle size analysis Test group 1/1

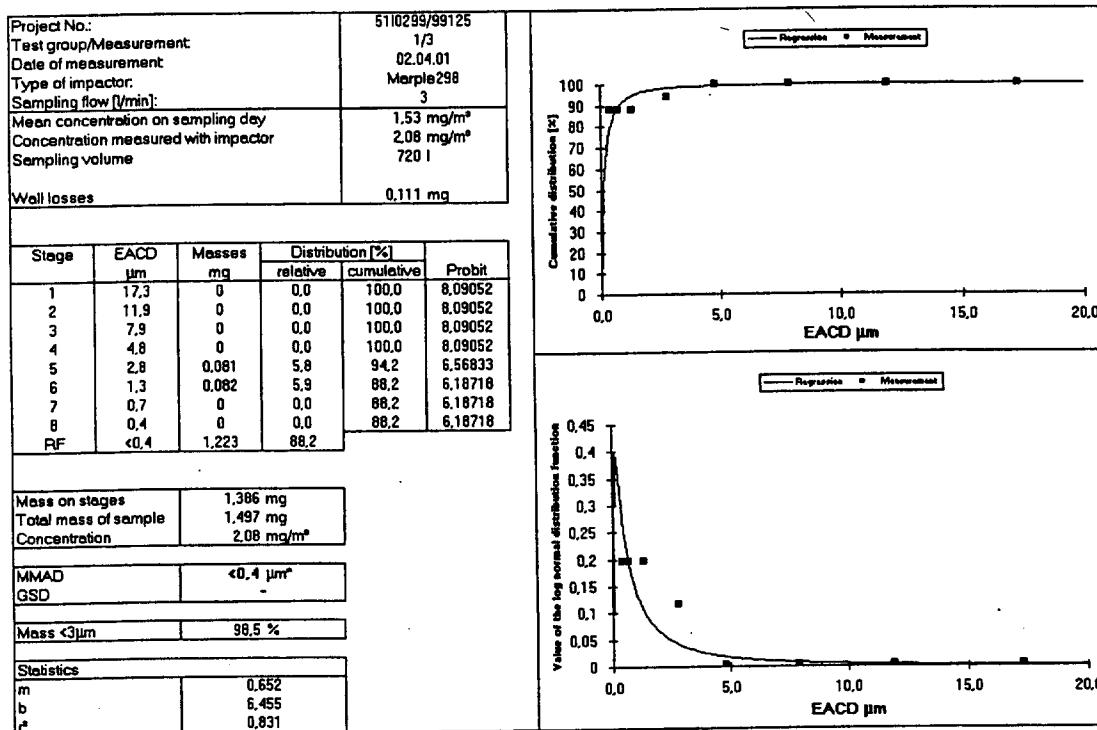


**Table IIC-006**  
Particle size analysis Test group 1/2

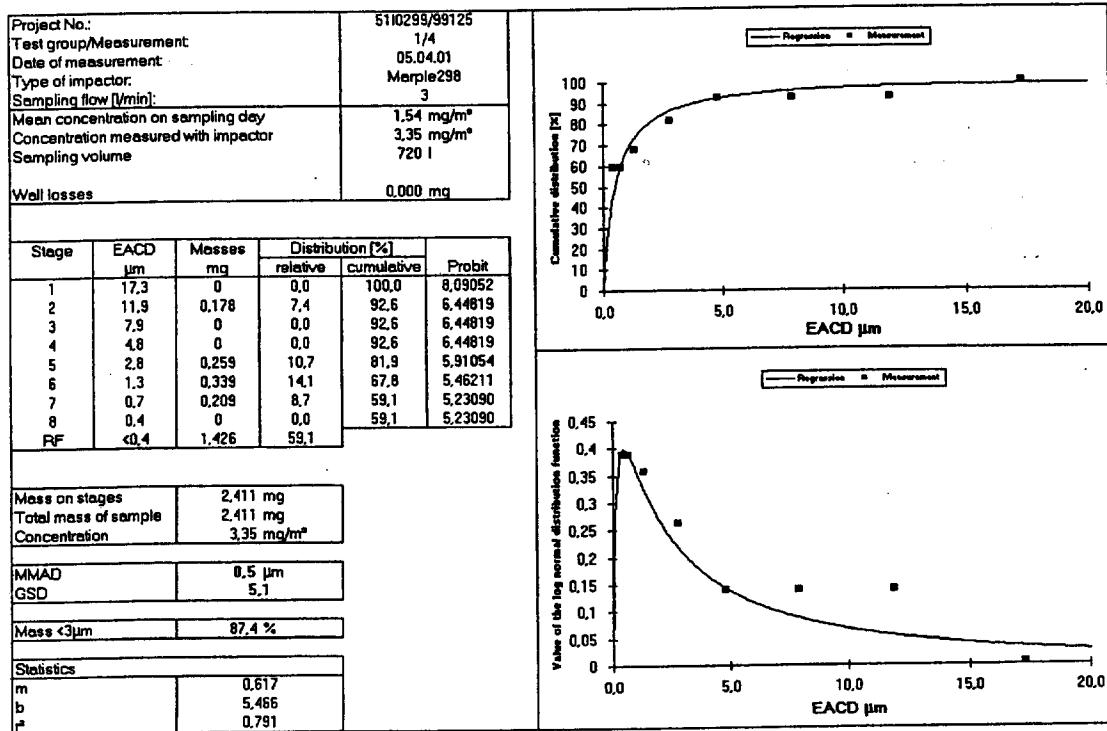


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**Table IIC-007**  
Particle size analysis Test group 1/3

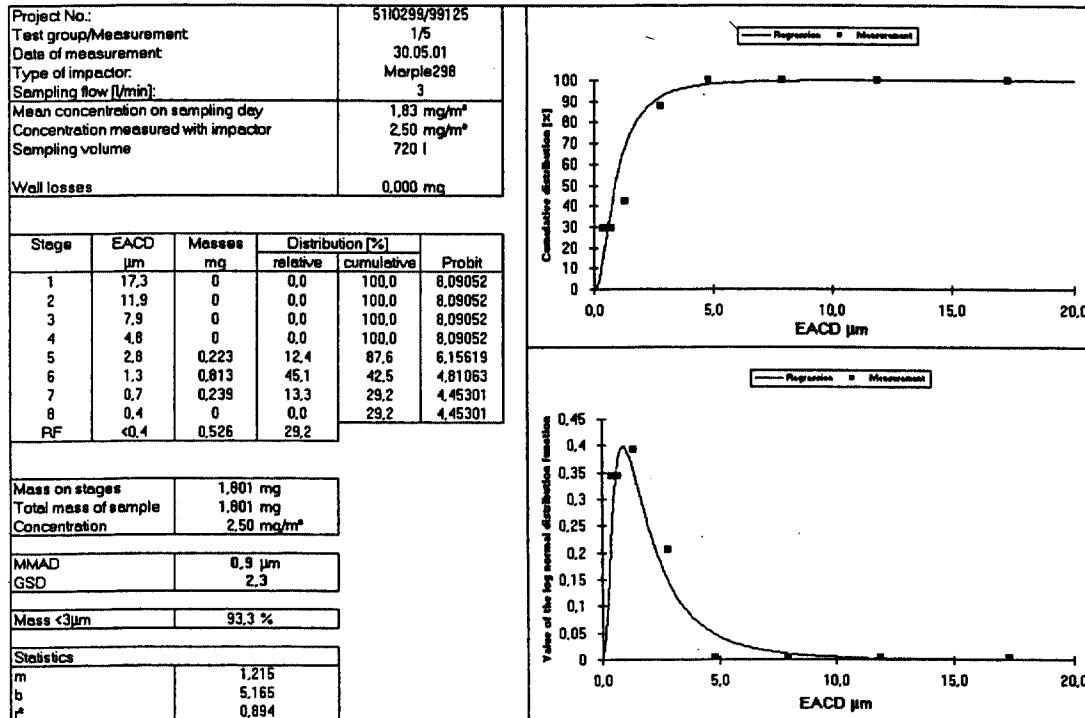


**Table IIC-008**  
Particle size analysis Test group 1/4

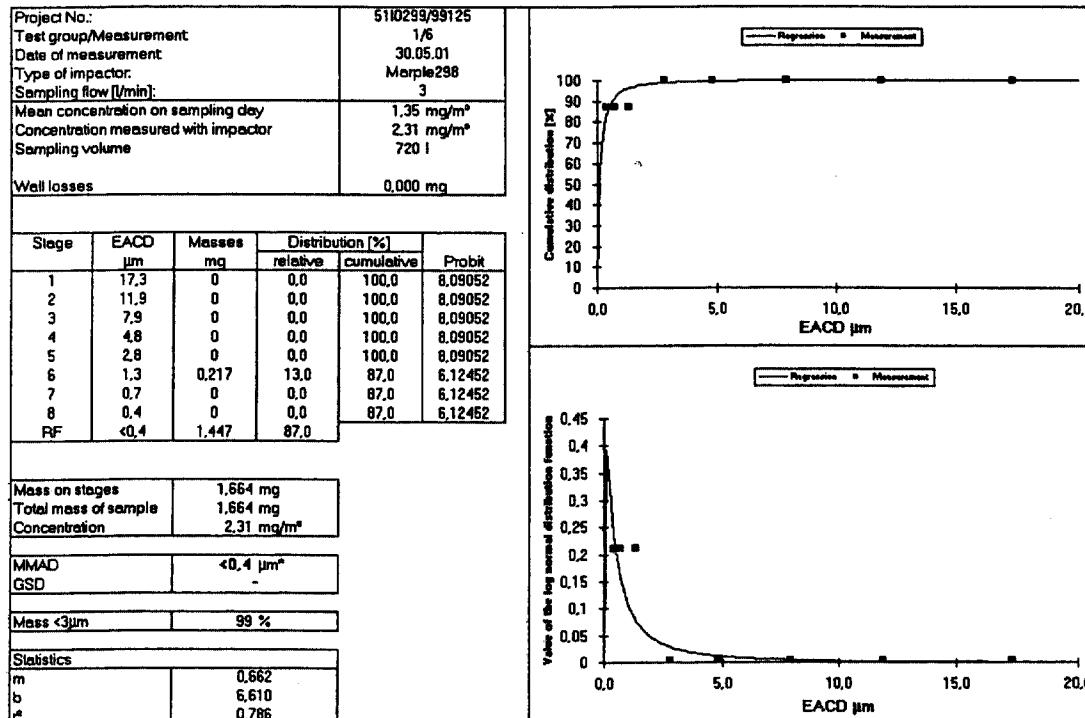


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**Table IIC-009**  
**Particle size analysis Test group 1/5**

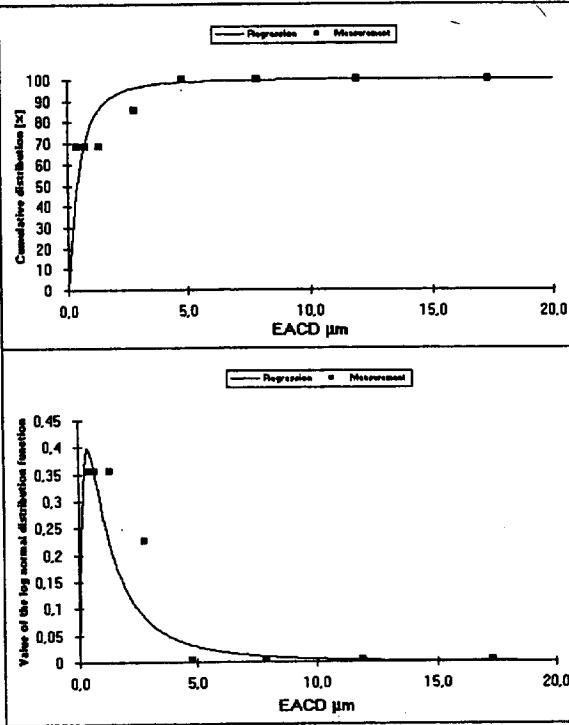
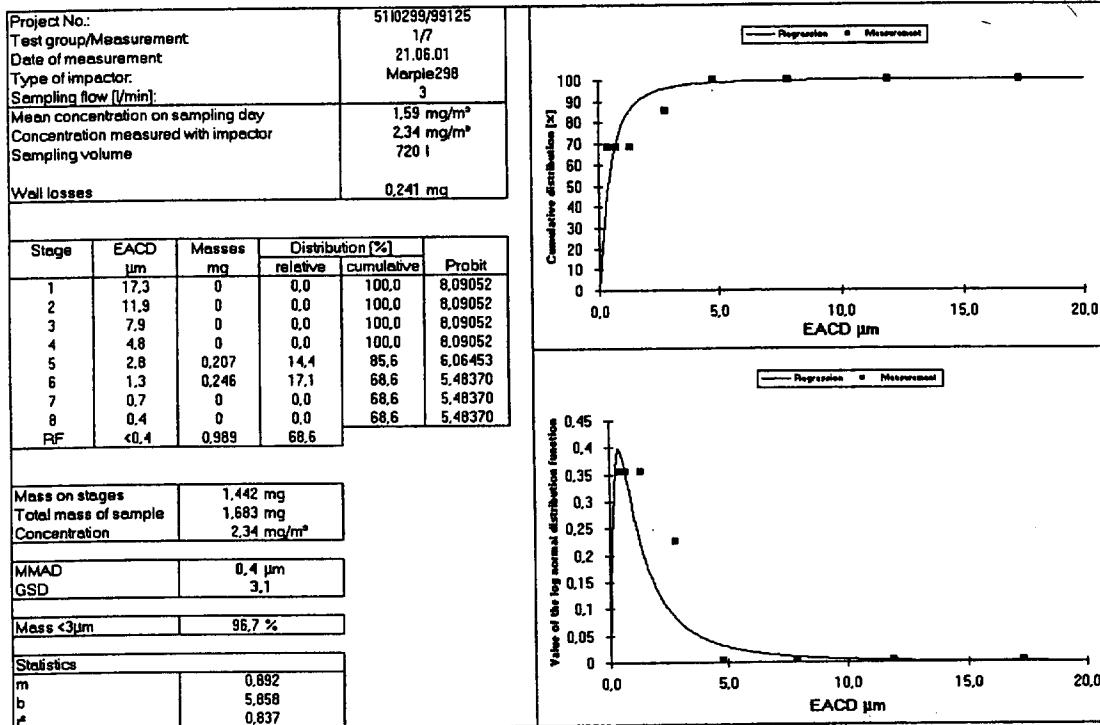


**Table IIC-010**  
**Particle size analysis Test group 1/6**

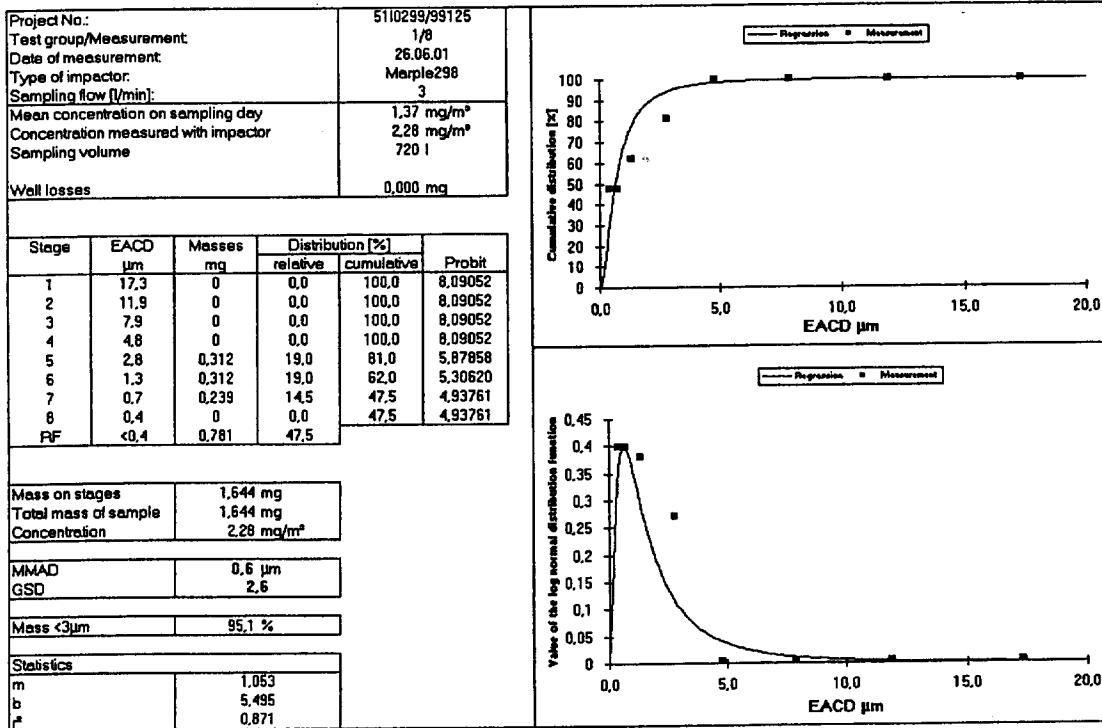


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**Table IIC-011**  
Particle size analysis Test group 1/7

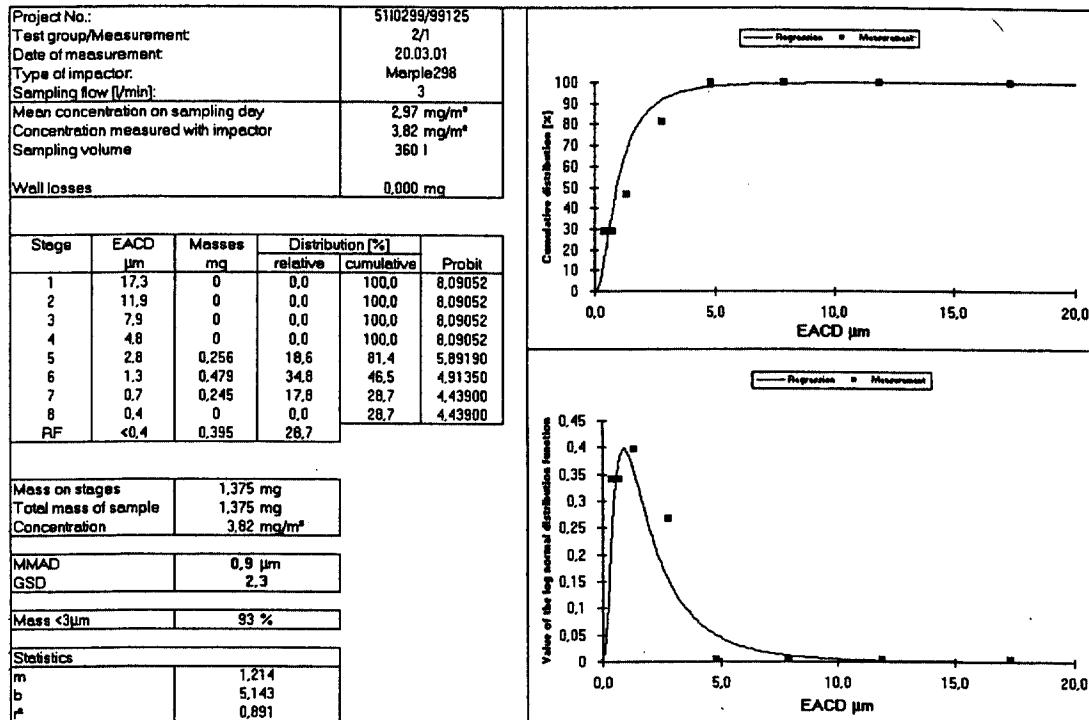


**Table IIC-012**  
Particle size analysis Test group 1/8

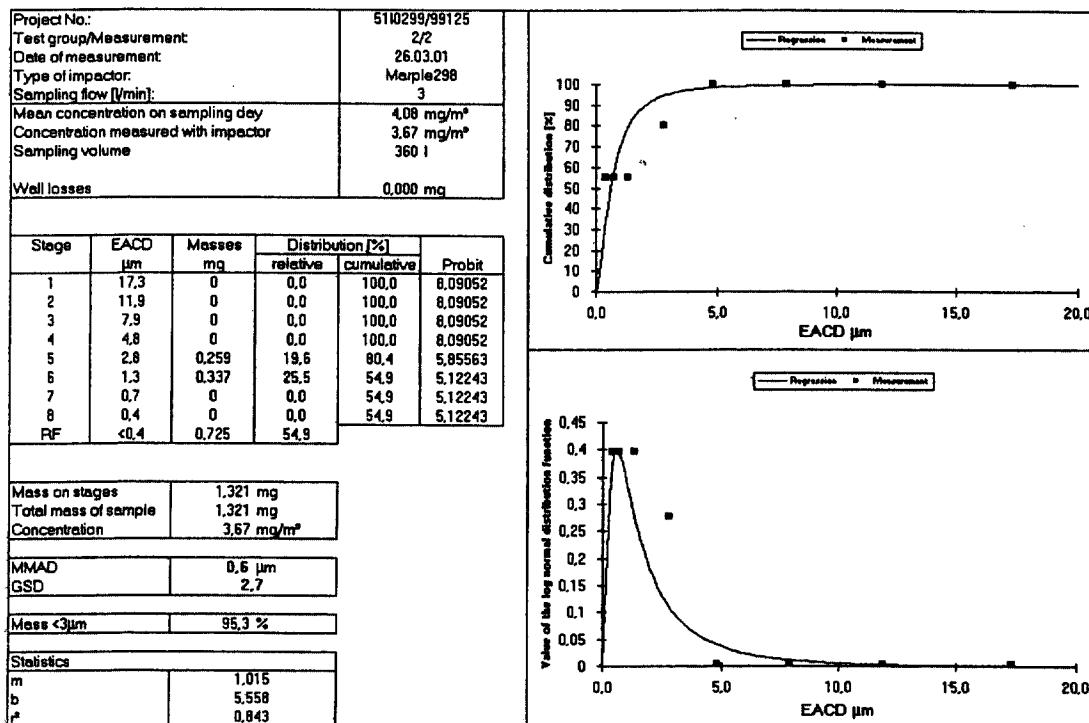


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**Table IIC-013**  
Particle size analysis Test group 2/1

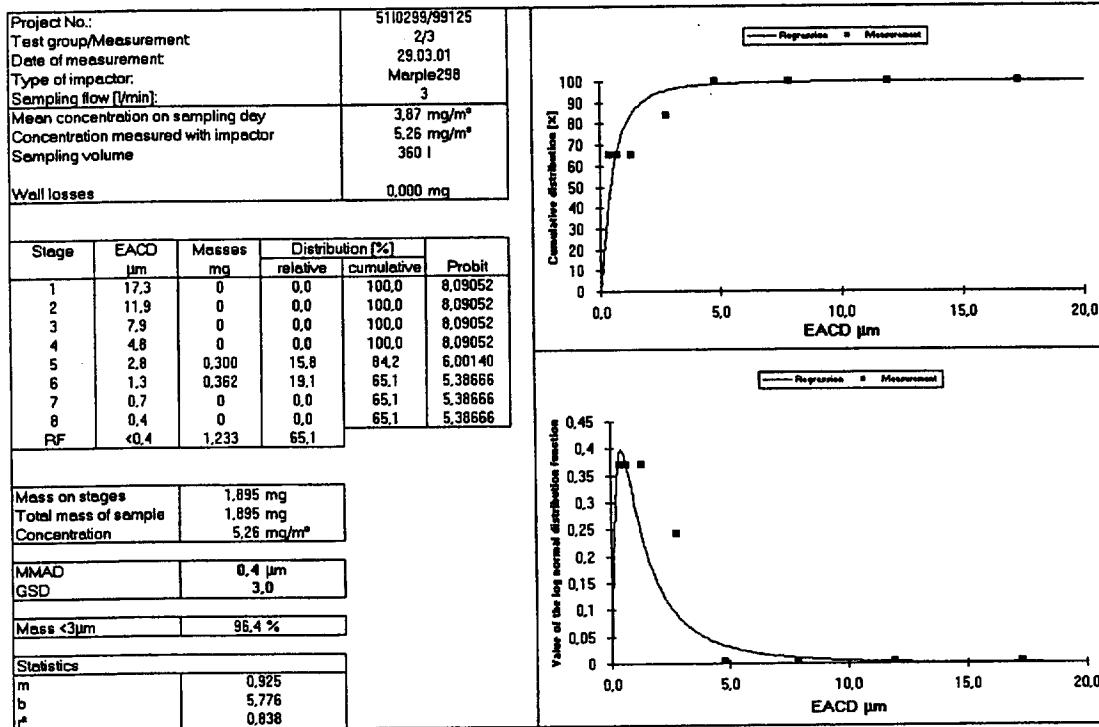


**Table IIC-014**  
Particle size analysis Test group 2/2

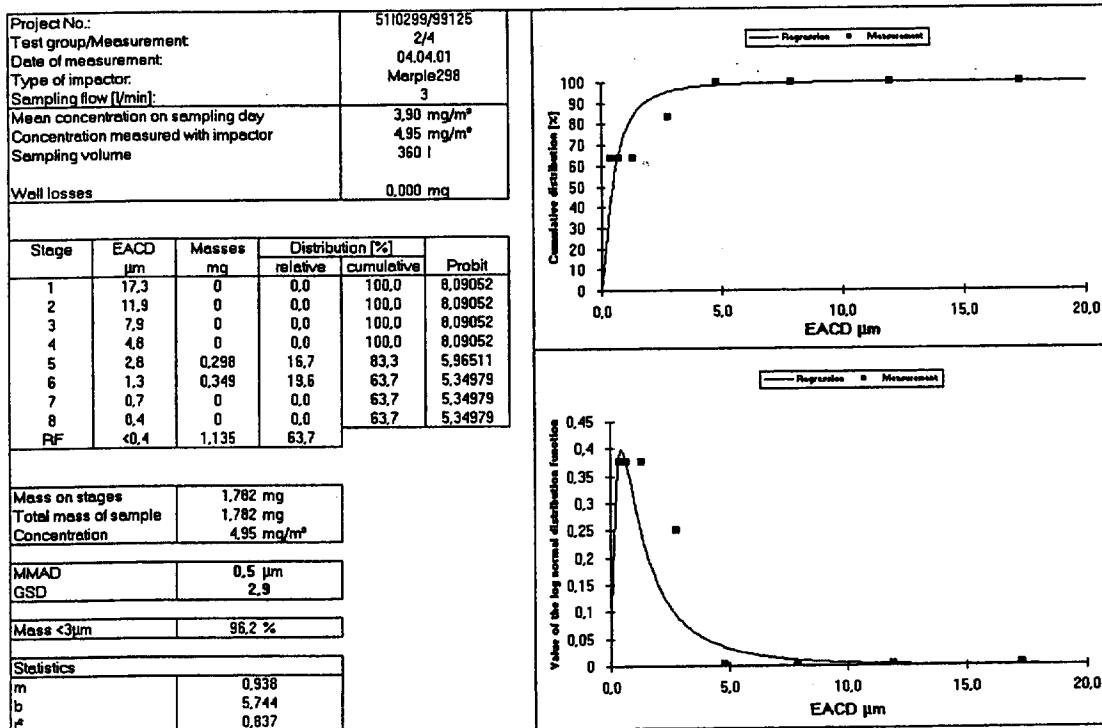


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**Table IIC-015**  
Particle size analysis Test group 2/3

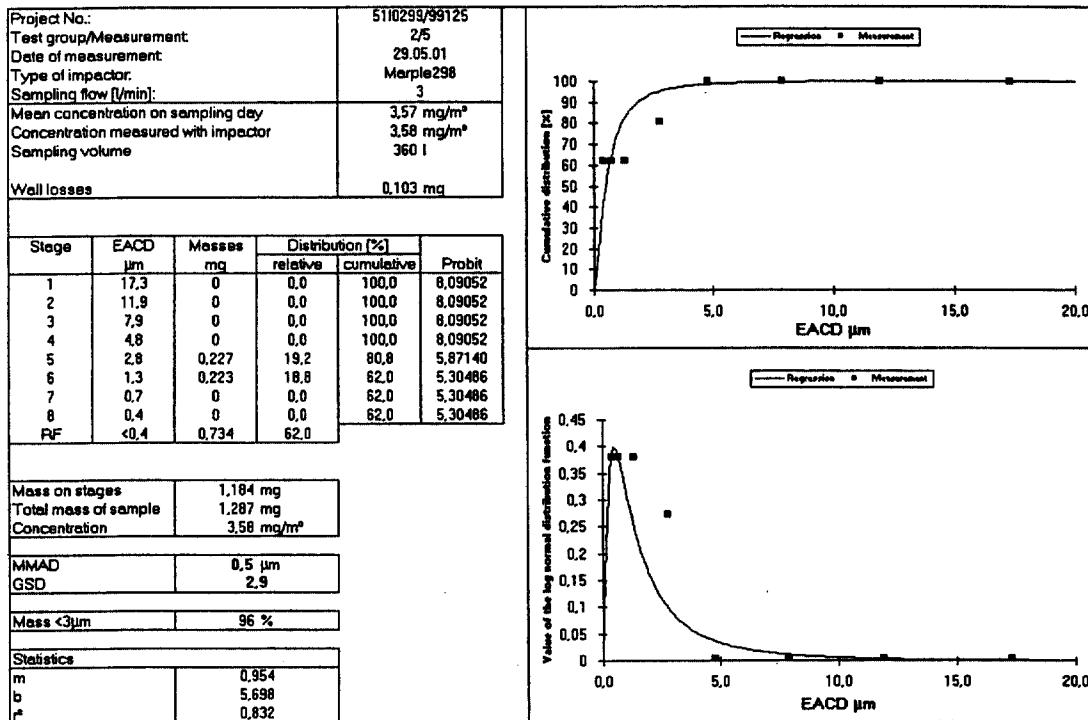


**Table IIC-016**  
Particle size analysis Test group 2/4

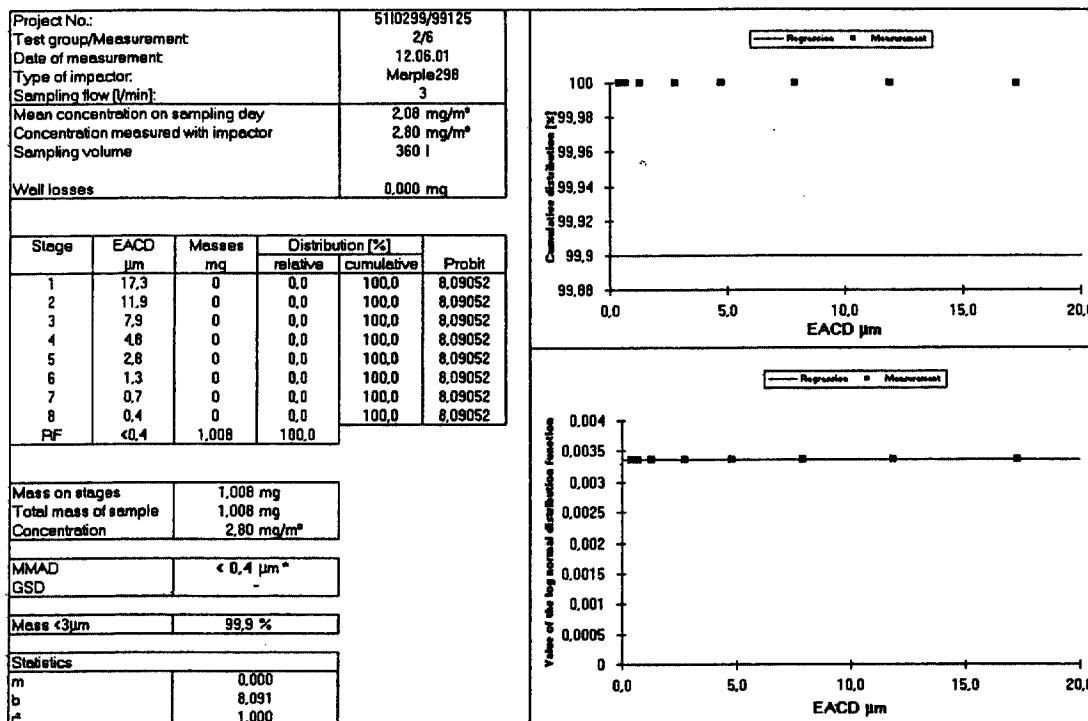


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**Table IIC-017**  
Particle size analysis Test group 2/5

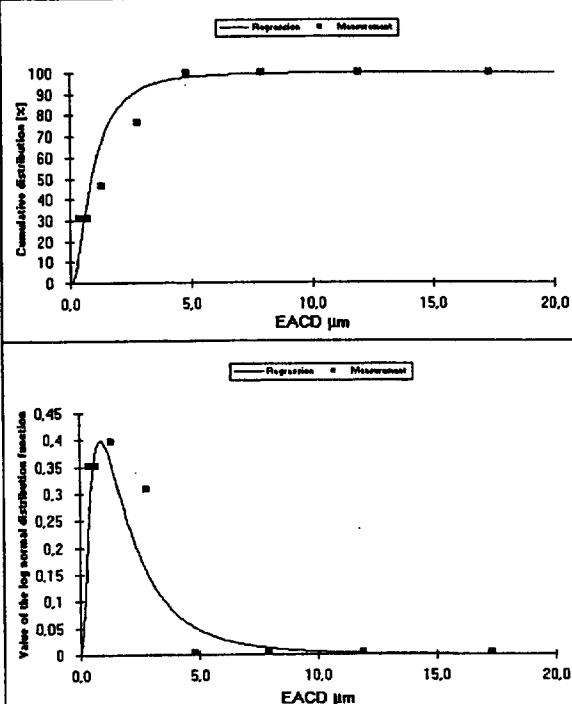
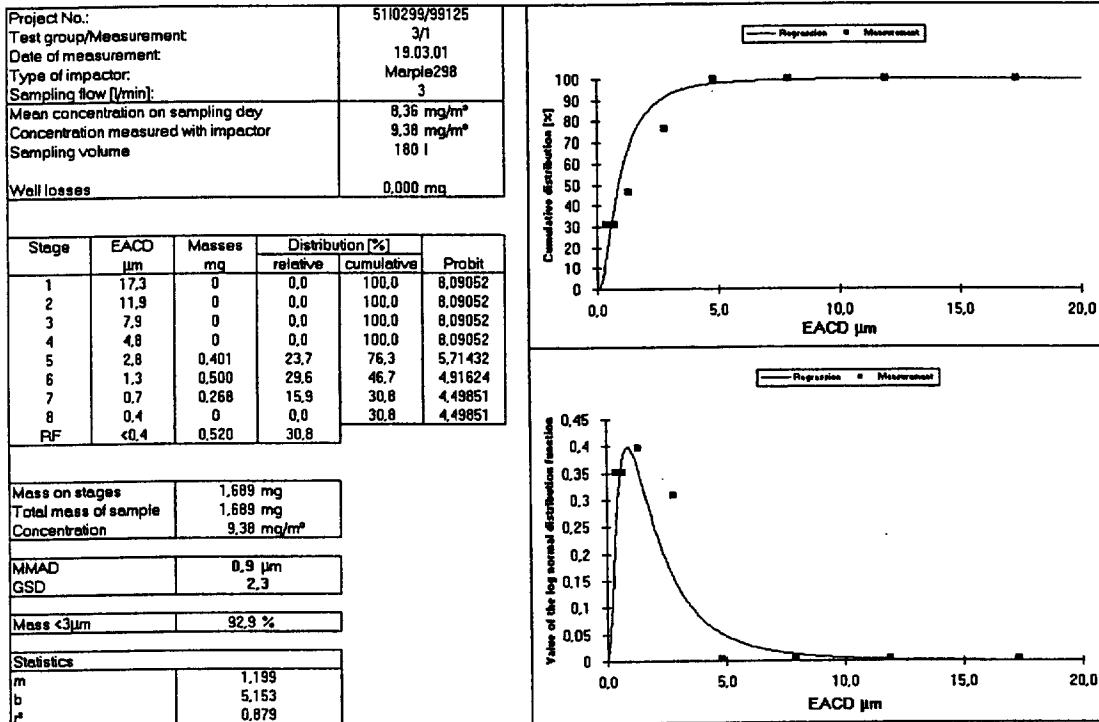


**Table IIC-018**  
Particle size analysis Test group 2/6

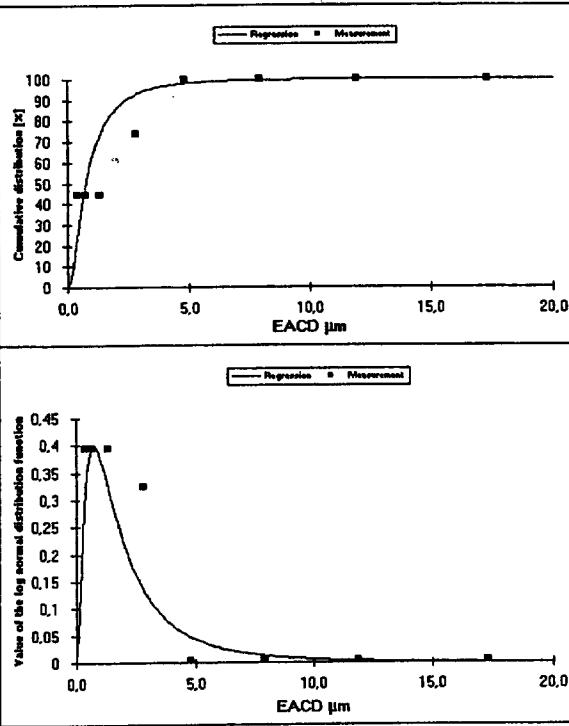
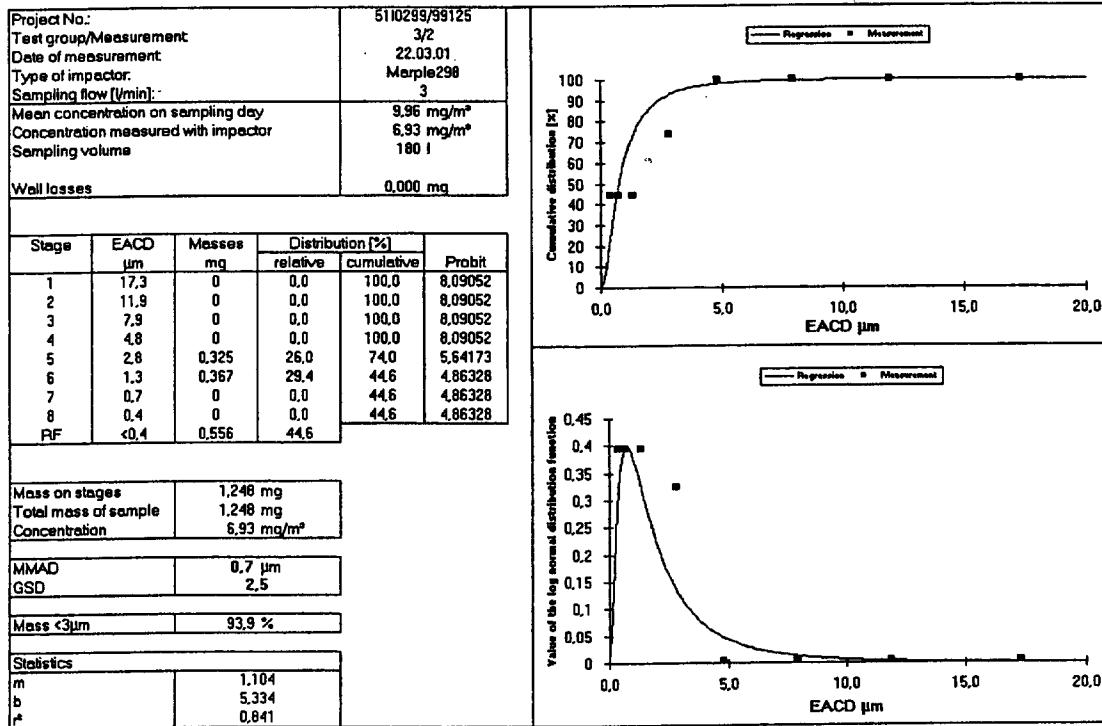


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**Table IIC-019**  
Particle size analysis Test group 3/1

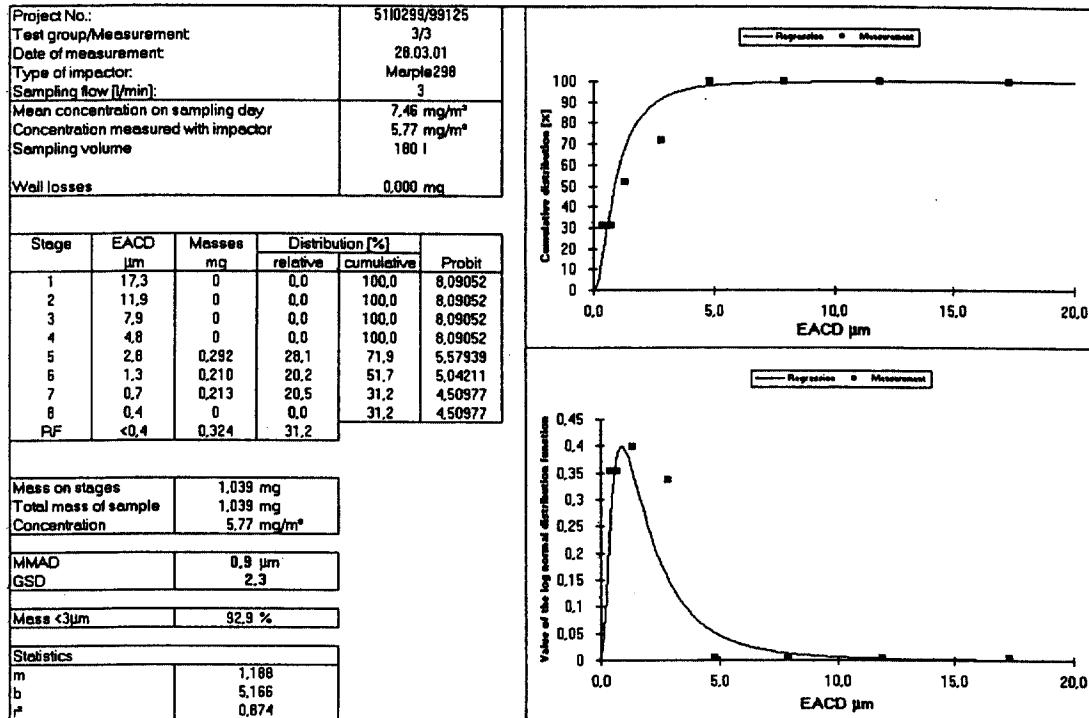


**Table IIC-020**  
Particle size analysis Test group 3/2

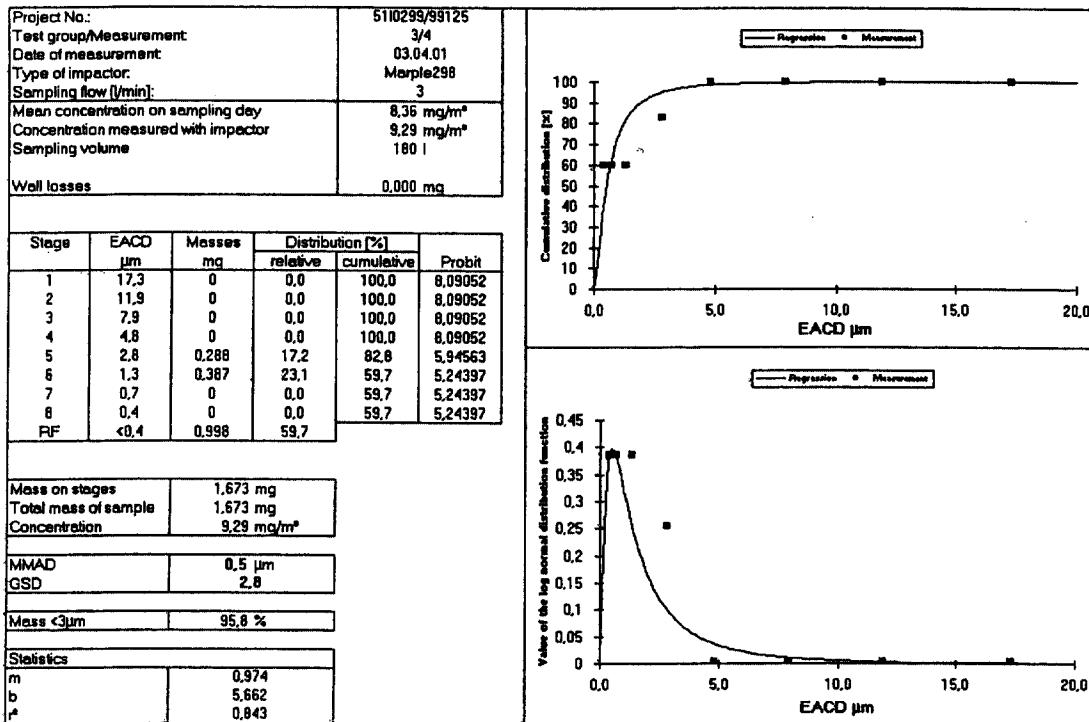


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**Table IIC-021**  
Particle size analysis Test group 3/3

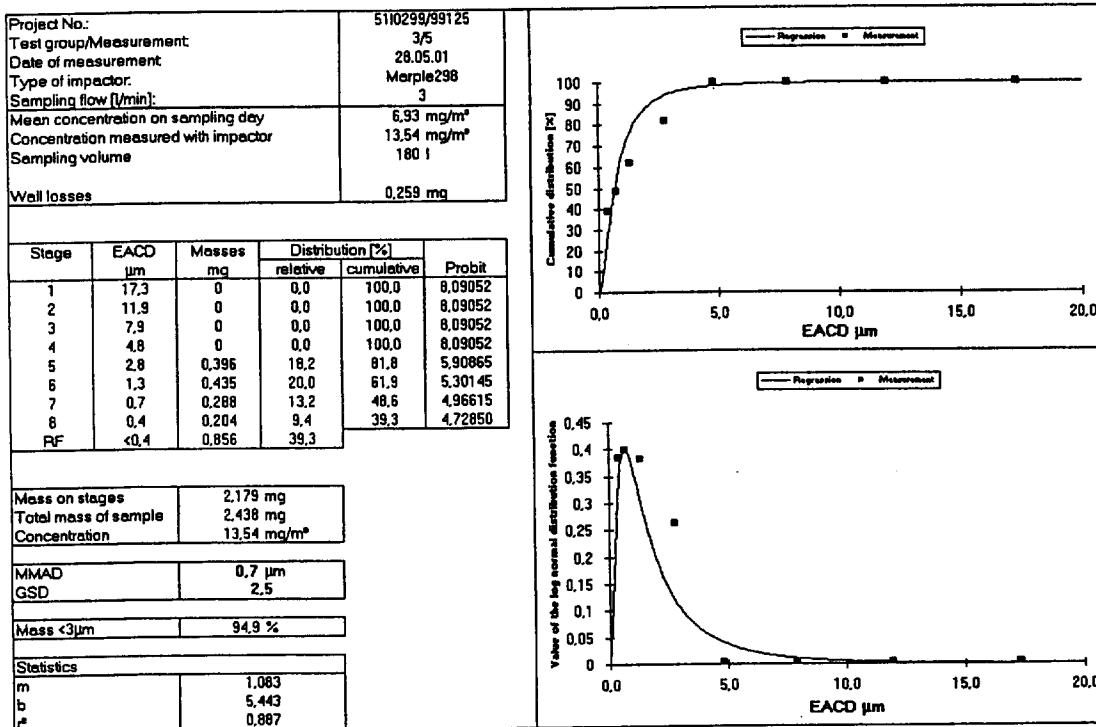


**Table IIC-022**  
Particle size analysis Test group 3/4

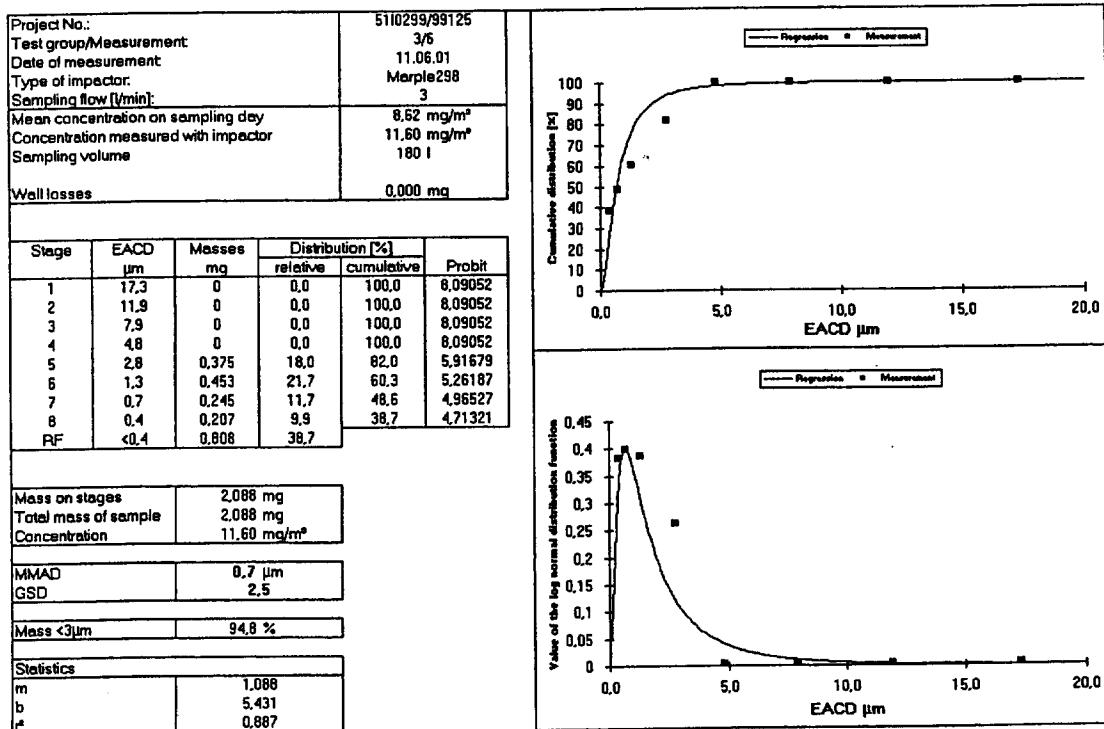


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**Table IIC-023**  
**Particle size analysis Test group 3/5**



**Table IIC-024**  
**Particle size analysis Test group 3/6**



**STUDY TITLE**

Report

**Diethanolamine - Subchronic inhalation toxicity study in Wistar rats**  
liquid aerosol / vapor exposure  
Study focus on irritation of upper respiratory tract

**PERFORMING LABORATORY**

Experimental Toxicology and Ecology  
BASF Aktiengesellschaft  
67056 Ludwigshafen/Rhein, Germany

**LABORATORY PROJECT IDENTIFICATION**

51I0299/99125

**SPONSOR**

CEFIC Amines Sector Group  
Avenue E. Van Nieuwenhuyse 4  
B- 1160 Brussels

**VOLUME III OF III  
(SUPPLEMENT)**

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Analysis of the substance; see report of Dow Chemical Company	1 page

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SAI0299199125

Certificate 600966

The Dow Chemical Company

Page 1

Date: 22.02.2001

Certificate of Analysis

SHIPMENT COPY

DOW DEUTSCHLAND GMBH & CO. OHG  
CARGO CITY SUD/GEBÄUDE 556  
FRANKFURT FLUGHAFEN 06 60549

Fax:  
GERMANY

Cust P.O.: 30/19/40)16193

Divy Note: 66532365 10

Material: DIETHANOLAMINE

Cust Mtl:

Batch: og1701A9 11

Vehicle: FOFZ/CIRILE

Ship from: THE DOW CHEMICAL COMPANY PLAQUEMINE LA UNITED STATES

This material meets the requirements of the specification.

Feature	Units	Results og1701A9u1	Limits		Method
			Minimum	Maximum	
Assay	g	99,89	99,30	----	DOWM 100095
Monoethanolamine	g	0,03	----	0,45	DOWM 100095
Triethanolamine	g	0,02	----	0,25	DOWM 100095
Equiv. Wt., Appt.	-	105,1	104,0	106,0	DOWM 100253
Water	g	0,07	----	0,15	ASTM E203-96
Color, Pt-Co	--	3	----	15	ASTM D1209-97
Appearance		Passes	----	----	Visual

Specialty Alkanolamines Lab Tech.  
QA/QC Lab

For inquiries please contact Customer Service or local sales.  
USA: 800-232-2436 Canada: 800-363-3500 English 800-363-8700 French

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